REPORT OF THE
DEPARTMENT OF HEALTH PROFESSIONS
VIRGINIA STATE POLICE

PRESCRIPTION MONITORING PROGRAM

TO THE GOVERNOR, CHAIRMEN OF THE HOUSE COMMITTEE ON HEALTH, WELFARE, AND INSTITUTIONS AND THE SENATE COMMITTEE ON EDUCATION AND HEALTH

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Preface

Chapter 481 of the 2002 Acts of Assembly amended the *Code of Virginia* to implement a prescription monitoring program for Schedule II controlled substances dispensed in Southwest Virginia. The legislation also required the Director of the Department of Health Professions (DHP) and the Superintendent of the Virginia State Police (VSP) to submit an evaluation of the program to the General Assembly two years after implementation. DHP was required to secure federal or other funding to cover the costs for implementation and initial operation of the program. DHP secured a federal grant in April 2003 for this purpose. The program requires dispensers of Schedule II controlled substances to report twice monthly to a contractor who screens the data for completeness and validity according to established standards. The contractor then supplies the data to DHP to be placed into a secure and separate database. Access to the data is limited by law for very specific purposes and to specific groups or persons.

This document is the evaluation of the program after its first year of operation. The grant awarded for implementation of the program will expire at the end of July 2005 prompting the necessity for the early submission of this report.

Sincere thanks and gratitude to the individuals who serve on the Prescription Monitoring Program Advisory Committee, the staff of the DHP and VSP, as well as other interested parties for their participation and assistance in developing an evaluation plan, for reviewing data concerning the program, and developing recommendations to improve the efficiency and efficacy of the program.

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Director,
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Executive Summary

Chapter 481 of the 2002 Acts of Assembly amended the *Code of Virginia* to create a prescription monitoring program as a pilot program limited to State Health Planning Region III in Southwest Virginia. The Department of Health Professions was awarded a federal grant through the Harold Rogers Prescription Drug Monitoring Program to implement and support initial operations of the program in April 2003. An additional grant was awarded in 2004 for the purposes of sponsoring a conference on prescription drug abuse and prescription monitoring programs and to conduct a survey of practitioners regarding the prescribing of controlled substances and their impressions of the program.

In June 2003, the Director formed an advisory committee to assist in the implementation and evaluation of the program. The committee advises the Department on the extent to which the legislation has been successfully implemented, any changes that should be made in policies and practices of the program, what aspects of the program should be evaluated and any other issues related to the illegal diversion of controlled substances or access to appropriate drug therapy. The committee has met quarterly beginning in September 2003 and has been instrumental in developing an evaluation workplan for the program, determining policy issues and making recommendations resulting from the review of these issues.

The program began operations in September 2003 with prescriptions dispensed for Schedule II controlled substances being submitted by approximately 300 pharmacies and other dispensers twice a month. Currently, the database contains over 460,000 prescription records and over 1000 requests for information from the program have been processed.

Review of data collected thus far appears to show that the implementation of the program has not had a "chilling" effect on the legitimate prescribing of Schedule II controlled substances. The amount of oxycodone and hydrocodone being distributed in wholesale distribution channels continued to increase throughout Virginia at a rate of 9% and 8% respectively in 2002 and 2003. Information maintained by the Department of Medical Assistance Services (DMAS) shows that after a substantial drop in claims for oxycodone containing prescriptions in the 1st and 2nd quarters of 2002, the number of claims submitted in the 1st quarter of 2004 for these products are 21% higher than they were in the 1st quarter of 2001. A survey was conducted in mid-2004 and compiled by the Survey and Evaluation Research Laboratory, Virginia Commonwealth University and sponsored by the American Cancer Society (ACS) and the South Atlantic chapter

of the ACS, in collaboration with the Virginia Cancer Pain Initiative. Physicians were asked if in the past three years, they have been prescribing fewer Schedule II controlled substances. 36% of respondents reported prescribing fewer Schedule II drugs; of these, 48% cited intense media coverage and 41% cited increased law enforcement activity as the reason for prescribing fewer Schedule II prescriptions. 31% of these practitioners reported that prescribing fewer Schedule II drugs had a negative impact of helping patients manage their pain while 61% reported no impact.

A concern of having a pilot program in only the southwest portion of the Commonwealth was that the illegal activity of prescription drug diversion would move to outside the program area. Data from the Drug Diversion Unit of the State Police appears to confirm that concern. Data comparing 2003 to 2004 shows complaints received by the unit increased by 26% statewide while decreasing in the program area by 47%. Arrests increased by 35% statewide versus 31% in the program area. It also appears that using the program may save substantial man-hours in performing investigations with data from the program area showing a 53% decrease in man-hours spent doing pharmacy profiles between 2003 and 2004.

Accidental deaths due to prescription drug abuse or misuse continues to be a significant public health concern in Virginia, especially the southwest region of the Commonwealth. Since 2000, there has been a 100% increase in drug deaths in the Western District of the Office of the Chief Medical Examiner. Statewide in 2003, there were 223 drug deaths reported in the Western District, 101 in the Tidewater District, 106 in the Central District and 108 in the Northern District. In the Western District, 44.6% of the cases identified methadone as the cause of death followed by hydrocodone, oxycodone, fentanyl and propoxyphene.

The issue of prescription drug abuse is not limited to Virginia. The President's 2004 National Drug Control Strategy highlighted the problem, reporting that the non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past-month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. To combat this problem several approaches are being developed, including education and training on appropriate pain management and opioid treatment procedures for practitioners, increasing the number of state prescription monitoring programs, and using technology to

identify, investigate, and prosecute “pill mills” including internet pharmacies that provide controlled substances illegally.

In May 2004, Department staff developed a list of policy issues that became evident as a result of the evaluation workplan. These policy issues were reviewed at the June and September 2004 meetings of the Advisory Committee and recommendations were made based on those issues.

Limitations in Coverage: The program in its current form has two limitations in coverage which make it less than effective. First, the program is limited geographically to pharmacies in Southwest Virginia (Health Planning Region III). This means that pharmacies outside of this area do not report to the program. This gives an incomplete picture of what a patient may be receiving or a prescriber may be writing. For example, several prescribers querying the system have reported that although the system showed no prescriptions filled for a particular patient, they knew that they had written prescriptions for that patient. The patient is most likely having the prescriptions filled by a pharmacy outside the geographical area, or by a mail order pharmacy which is not covered by the current program. Individuals who engage in "doctor shopping" for the purpose of obtaining controlled substances for illicit use are very savvy about drug laws, frequently travel many miles to visit numerous physicians and pharmacies, and will avoid having their prescriptions filled in pharmacies within the program area to prevent detection.

Second, the program is limited in scope, only covering prescriptions written for drugs classified in Schedule II. While by definition Schedule II drugs have the greatest potential for abuse, it has been reported by those who deal with illicit pharmaceutical diversion that most abuse occurs in other schedules. Data shows that hydrocodone products such as Vicodin or Lortab, Schedule III drugs, are more often abused in Virginia than Schedule II drugs. Benzodiazepine products, such as Valium or Xanax, Schedule IV drugs, are also frequently abused, often in combination with other products. Because pharmacies only report Schedule II prescriptions, prescriptions filled for these other scheduled drugs are not captured and the program is defeated. Again, street-smart doctor shoppers and physicians running "pill mills" are aware of the program and will avoid prescriptions for Schedule II drugs to prevent detection.

Access to the Data: The Virginia PMP appears to be the most restrictive prescription monitoring program in the nation in terms of limiting access to the prescriber and dispenser. In

other states up to 90% of all queries come from prescribers who query monitoring systems for the purpose of "establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient." This allows a prescriber to avoid being duped into providing drugs to individuals for illegitimate purposes and to detect a patient who has a serious substance abuse problem. It also allows a prescriber to refer a patient for treatment, change prescriptions, or otherwise provide better medical care. However, Virginia law requiring a patient's written, informed consent adds to the significant burden that currently exists in a busy physician's office and makes this important feature of drug monitoring less useful. Also, under Virginia law, a dispenser (pharmacist) is not authorized to query the system at all. This is not the case in most other states' programs. The ability of pharmacists to query the system when a questionable prescription is presented can prove to be a great aid in meeting their obligation to dispense only for an appropriate medical purpose.

Wording in the law restricts access to the personnel of the Department of Health Professions to cases relating to indiscriminate prescribing and dispensing. Investigators from the State Police, in addition to requesting information related to prescribing and dispensing, may also request information related to a patient. DHP staff has authority in law to obtain prescription information through traditional means on licensees of DHP who are under investigation for personal drug diversion or misuse as recipients, and should also be able to access the program in these same cases to streamline case investigation time and reduce man-hours.

Analysis of the data maintained by the program: Current law does not permit any entity, including DHP, to examine the prescription information that is in the system. In the first year of data collection the Department compiled over 400,000 records of Schedule II drugs in the covered area. It is likely that careful analysis of this data can contribute to identification of poor practice and illegal activity. Needless to say, such analysis and use of the information contained in this system must be carefully crafted in such a way as to not inhibit the appropriate delivery of care nor result in unfair and unfounded accusation of violations of law or regulation.

Nevada's administration of its more developed prescription monitoring effort has resulted in a significant reduction in "doctor shopping" by analyzing the data for the purpose of providing unsolicited reports of possible "doctor shopping" to physicians about their patients. Nevada has

developed strict criteria for identifying possible criminal drug diversion based on the number of physicians that one patient may see and numbers of controlled substances obtained. The criteria have been designed to screen out patients seeing multiple physicians for legitimate medical purposes. The "medical model" of providing information to those prescribers may be the greatest benefit in achieving a reduction in prescription drug abuse. Virginia law does not currently authorize the analysis of the data for this purpose.

Funding: At the current time the program is operating on funds generated from federal sources. It also appears that unmatched grants maybe available for the next several years to continue operation of this program. However, there is no guarantee that this situation will continue indefinitely. If the state finds that this program is effective in helping to address the serious and growing problem of prescription drug abuse in the Commonwealth, a commitment to fund this activity should be addressed.

Practitioner education: A question has been raised concerning what a practitioner can do and what his responsibility is for a patient who appears to be "doctor-shopping" or is abusing prescription controlled substances. While a common occurrence is the discharge of the patient from the practice or the refusal to write a prescription, the practitioner and the patient may benefit from the practitioner having access to guidance on referring for treatment, when and how to report suspicions of criminal activity to law enforcement, and how to properly manage a patient receiving treatment with controlled substances.

The recommendations of the Advisory Committee as endorsed by the Department of Health Professions and the Virginia State Police are as follows:

1. Continue the program indefinitely;
2. Expand the program to include Schedule II through IV controlled substances;
3. Expand the program to the entire Commonwealth;
4. Allow pharmacists to access the program;
5. Allow a prescriber licensed in another state to request information from the PMP;
6. Allow access to the PMP for DHP investigative personnel and designated HPIP personnel on a specific licensee, registrant, or certificate holder where there is an open investigation;
7. Allow Medical Examiners access to the PMP for the purpose of performing their duties in accordance with §32.1-283;

8. Allow access to The Department of Medical Assistance Services for the purpose of investigating fraud when there is an open investigation on a recipient;

9. Allow access to the Drug Enforcement Agency when there is an open investigation on a prescriber or dispenser;

10. Allow access to the program for research purposes to public and private entities where all personal identifying information is removed;

11. Allow access to the program for health/education purposes, providing information to prescribers and dispensers on their patients who may be abusing, misusing, or fraudulently obtaining controlled substances ; and

12. Require non-resident pharmacies to report to the program.

A draft of the proposed legislation which embodies these recommendations is found in Appendix A.

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Authority for the Prescription Monitoring Program

Chapter 481 of the 2002 Acts of Assembly amended the *Code of Virginia* to create a prescription monitoring program in the Commonwealth of Virginia. The statute required the Director of the Department of Health Professions to establish the program in the southwest region of Virginia (State Health Planning Region III). The statute also required that the Director and the Superintendent of the State Police submit an evaluation of the program to the members of the House Health, Welfare and Institutions Committee and the Senate Education and Health Committee.

The program requires dispensers of Schedule II controlled substances to report the dispensing of prescriptions for these items to the Department twice monthly with certain exceptions. The exceptions include the dispensing of manufacturer samples, the administration of covered substances, dispensing by a practitioner of the healing arts in a bona fide emergency, dispensing to inpatients in hospitals, nursing facilities or hospices licensed by the Board of Health, and dispensing by veterinarians to animals.

Access to information from the program is limited under specific circumstances to prescribers, authorized agents of the State Police and the Enforcement Division of the Department of the Health Professions, other regulatory entities, agents of the Medicaid Fraud Unit of the Office of the Attorney General, and to recipients over the age of eighteen.

§ 2.2-3705 (78) of the Code of Virginia exempts data, records and reports relating to the program, the records collected and any materials related to the operation or security of the program from the Freedom of Information Act.

The statute also provide penalties for releasing information in the possession of the program or any data or reports produced or redisclosure or using the confidential information in any manner except as provided in the chapter.

Background on the Need for a Prescription Monitoring Program

The need for a prescription monitoring program became evident in 2001 when significant increases in deaths attributed to oxycodone abuse were reported in Southwest Virginia. Intense media coverage followed including reports on CBS's "60 Minutes" which reported in Lee County, "robberies were up 90 percent, five deaths in the previous six months had been linked to OxyContin, and despite wide media coverage there were reports of overdoses every other day." A survey of area students showed that "one-third of high school juniors and one in 10 seventh graders say they've at least tried what they call "Oxy's"." Additionally, the 2001 Facts and Figures Report of the Virginia Department of State Police stated that the Drug Diversion Unit ("DDU") received 2,164 complaints of diversion activities throughout the Commonwealth. As a result of these complaints, 1,738 investigations were initiated and a

total of 1,444 persons were arrested on 1,529 charges. These reports and others prompted then candidate for Governor Mark Warner to include in his platform the establishment of a prescription monitoring program. Senator William Wampler and Delegate Terry Kilgore sponsored legislation introduced in the 2002 General Assembly which was enacted and created the prescription monitoring program.

The problem of prescription drug abuse is not restricted to Virginia. A 2002 survey performed by the Maine Office of Substance Abuse found that 25% of high school seniors had misused prescription drugs and 10% of them had abused OxyContin. A University of Michigan study finding that "the abuse by high-school seniors of the brand-name narcotic Vicodin (a Schedule III controlled substance) is more than double their use of cocaine, Ecstasy, or OxyContin."

Other data from the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that between 1997 and 2002, the number of treatment admissions involving narcotic painkillers increased more than the overall increase in treatment admissions. This same report placed Virginia in a group of 31 states with an admission rate for narcotic painkillers of 24 or more per 100,000 aged 12 or older. The 2003 National Survey on Drug Use reports "the non-medical lifetime use of prescription pain relievers showed a five percent increase for the population 12 and older with young adults (18-25) experiencing a 15 percent increase in lifetime, as well as current use (compares 2002 and 2003 data)."

In 2004, the issue of prescription drug abuse has become so significant that it is prominently featured in the 2004 National Drug Control Strategy. "The strategy highlights the importance of prescription monitoring, and physician training, and education programs to curb the abuse of prescription drugs."

In a presentation given at the annual conference of the National Association of State Controlled Substance Authorities, Dr. Roger Cicala, who specializes in pain and addiction medicine and is the Assistant Medical Director of the Tennessee Medical Foundation, cited studies estimating that 25% of all prescription opiates are diverted. Additionally, a provider in a good pain management practice may expect that 10% of their patients are not legitimate and that it may take 3 to 6 months before those patients become apparent to the provider. This is where comprehensive prescription monitoring programs can be an invaluable tool in preventing these types of patients from obtaining prescriptions for controlled substances by fraud.

Prescription monitoring programs have been reported to have a deterrent effect on "doctor-shoppers," but the greatest effect on prescription drug abuse may be their use as a tool for prescribers. Prescribers that have access to these programs can verify a patient's controlled substance treatment history allowing them to make more informed treatment decisions. In some cases, it may allow a patient, who otherwise would not receive a prescription for a legitimate medical reason, to receive the medication.

Such information may also alert prescribers about patients who may need to have their treatment regimens altered or perhaps be referred for specialized care.

Additionally, "the effectiveness of prescription monitoring programs can be seen in a simple statistic: in 2000, the five states with the lowest number of OxyContin prescriptions per capita all had programs. According to the United States Drug Enforcement Agency, the five states with the highest number of prescriptions per capita lacked them." (2004 National Drug Control Strategy)

Law enforcement and licensing boards have also found prescription monitoring programs to be of assistance when investigating complaints. Without a prescription monitoring program, an officer or investigator must decide which pharmacies to visit to manually review prescription records to determine if a complaint is valid. This is extremely time-consuming and disruptive to the workflow in the pharmacies. By using a prescription monitoring program, the officer may request data on a patient, prescriber, or dispenser, review the data, and then narrow the number of pharmacies that must be contacted or visited. This process can result in substantial savings in man-hours for the agency.

Some states with prescription monitoring programs allow the data to be used for research and educational purposes. This information may be useful in determining trends of abuse which can assist in allocating resources such as law enforcement, treatment, intervention, and educational programs.

Evaluation of the Program

The legislation creating the prescription monitoring program requires an evaluation of the program be submitted to the members of the House Health, Welfare and Institutions Committee and the Senate Education and Health Committee after two years of operation. To assist with the evaluation of the program, the Director formed an advisory committee comprised of members from a wide range of interests and specialties. This committee has met quarterly since August 2003 and was instrumental in developing the evaluation workplan.

In reviewing literature about prescription monitoring programs, it was clear that data such as number of requests, arrests, and others were readily available. However, there appeared to be little data on how programs affect the legitimate medical use of controlled substances. There also appeared to be limited data that attempts to tie together available federal data with usage and abuse problems in the states with prescription monitoring programs.

Prescription Monitoring Program Database Statistics:

The prescription monitoring program began operation in September 2003. Prescriptions dispensed for Schedule II controlled substances are reported twice monthly to the contractor who checks the data for

accuracy, compiles the data into one file and forwards the file to the program to be placed into the program database.

After one year of operation, the database contains 413,809 prescription records and the program has processed 880 requests for information of which 760 were from prescribers, 75 from agents of the State Police Drug Diversion Unit and 44 from investigators with the Enforcement Division of the Department of Health Professions. One patient requested information on themselves during the year. The amount of prescriptions reported is double the original estimate and while it was expected that the number of requests would start off slowly, these are below expectations. Several factors may affect the request rate including the geographic limitation of the program and that the program only has information on prescriptions dispensed for Schedule II controlled substances. Additionally, according to a survey performed in May 2004 slightly less than half of physicians responding reported having heard of the program prior to receiving the survey. This is despite articles and advertisements in professional journals and presentations given at different meeting events over the last year. Some prescribers have stated that the consent requirements in the legislation and regulation were burdensome, and therefore they would not use the program.

Impact of the Program on the Legitimate Prescribing of Controlled Substances:

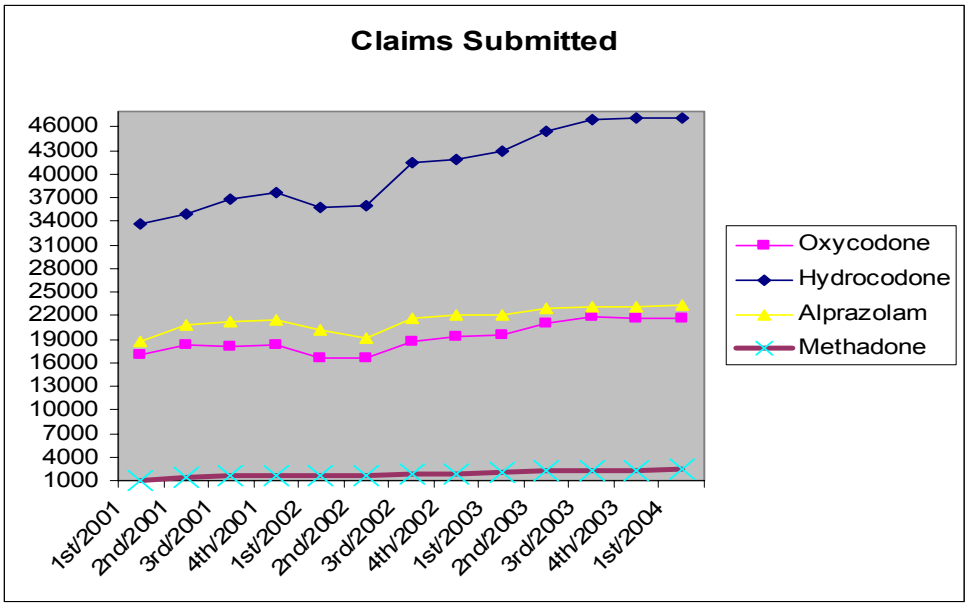
One of the concerns of the General Assembly and others was that a prescription monitoring program would have a "chilling" effect on the prescribing of controlled substances for legitimate medical purposes. The program received and reviewed data from the Department of Medical Assistance Services, Anthem Blue Cross and Blue Shield, and Automation of Reports and Consolidated Orders System (ARCOS) reports from the United Stated Drug Enforcement Agency's Diversion Control Program, which appear to indicate that this was not an effect of the program. The data does show that in mid-2002 there was a dip in the amount of prescriptions being dispensed, and the amount of certain Schedule II controlled substances being distributed to pharmacies; however, there was an overall increase for the entire period.

Other information that was tracked includes theft and loss reports from pharmacies, data from the State Police Drug Diversion Unit, data from the Office of the Medical Examiner, and a survey performed by the Survey and Evaluation Research Laboratory at Virginia Commonwealth University. Federal data sources were also reviewed as well as literature reviews in several publications.

Department of Medical Assistance Services:

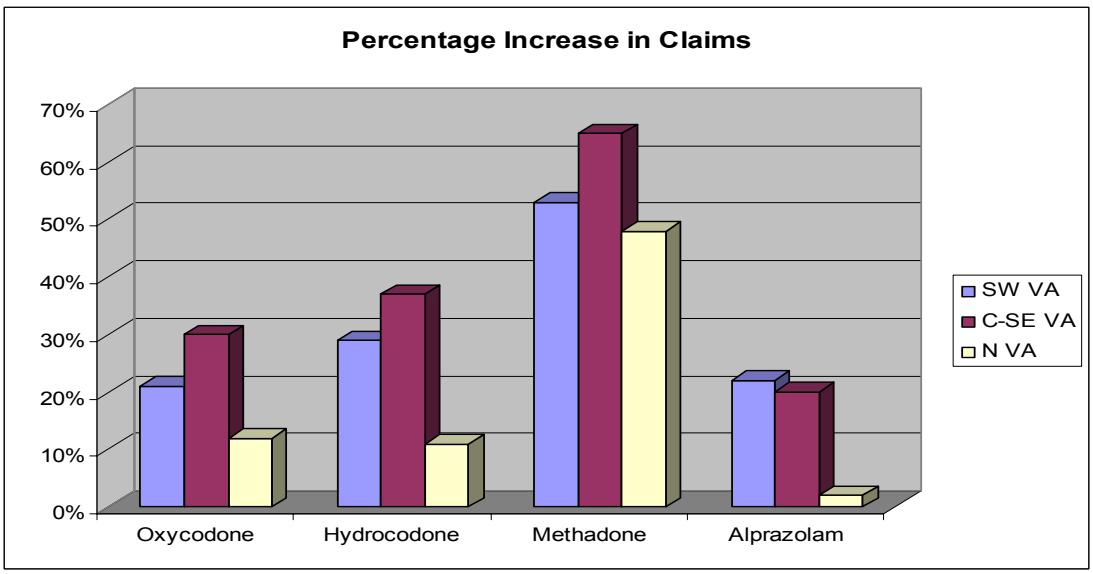
Over 550,000 Virginians receive prescriptions through the Department of Medical Assistance Services. Southwest Virginia has 30% of this population, central-southeast Virginia 49% and northern Virginia 21%.

Figure 1



The data shows a continuing increase in claims for oxycodone containing products (SCHEDULE II), methadone (SCHEDULE II), hydrocodone (SCHEDULE III) and alprazolam (SCHEDULE IV). The time period covered in this data is from January 1, 2001 through March 31, 2004.

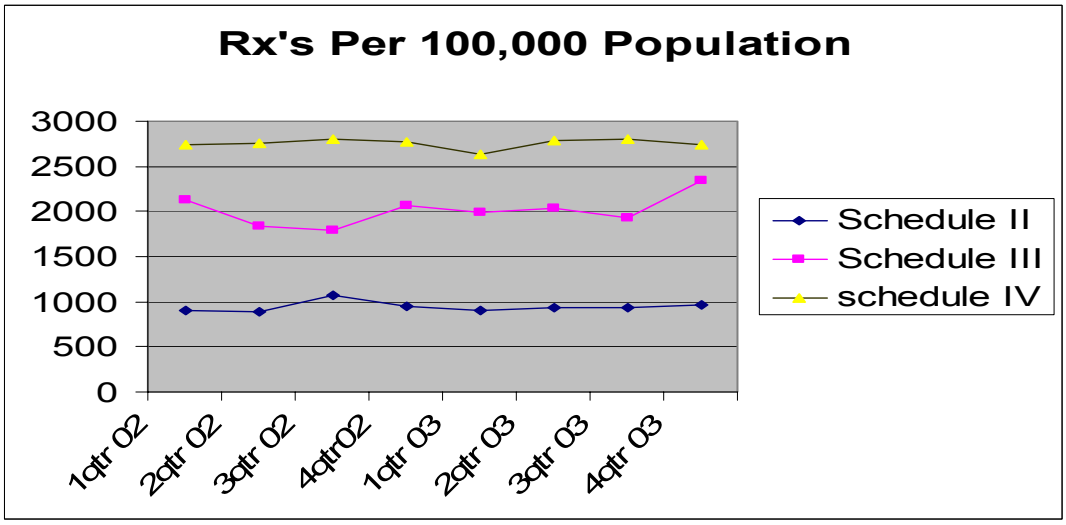
Figure 2



While the numbers of claims submitted for methadone are much smaller than for the other medications tracked, the percentage increase in the amount of claims is significant.

Anthem:

Figure 3

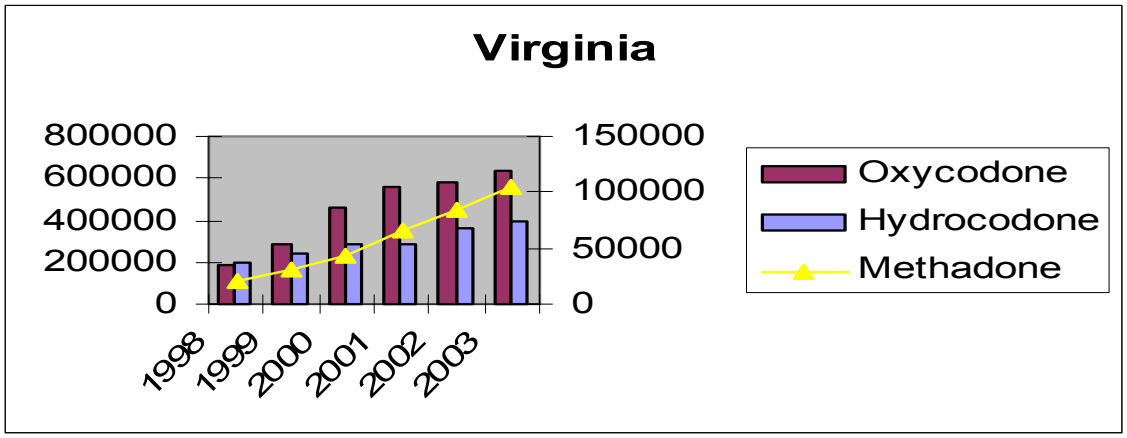


Anthem provided data on Schedule II-IV controlled substance prescriptions submitted for claims in the prescription monitoring area and the area immediately surrounding. Due to a change in software and collection methods, this is the only timeframe data was available. There appears to be little change in prescribing for these medications over the time period.

Automation of Reports and Consolidated Orders System (ARCOS)

ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing (retail) level. All Schedule I and II materials, Schedule III narcotic materials and selected Schedule III and IV psychotropic drugs transactions are tracked by ARCOS (DEA Diversion website).

Figure 4



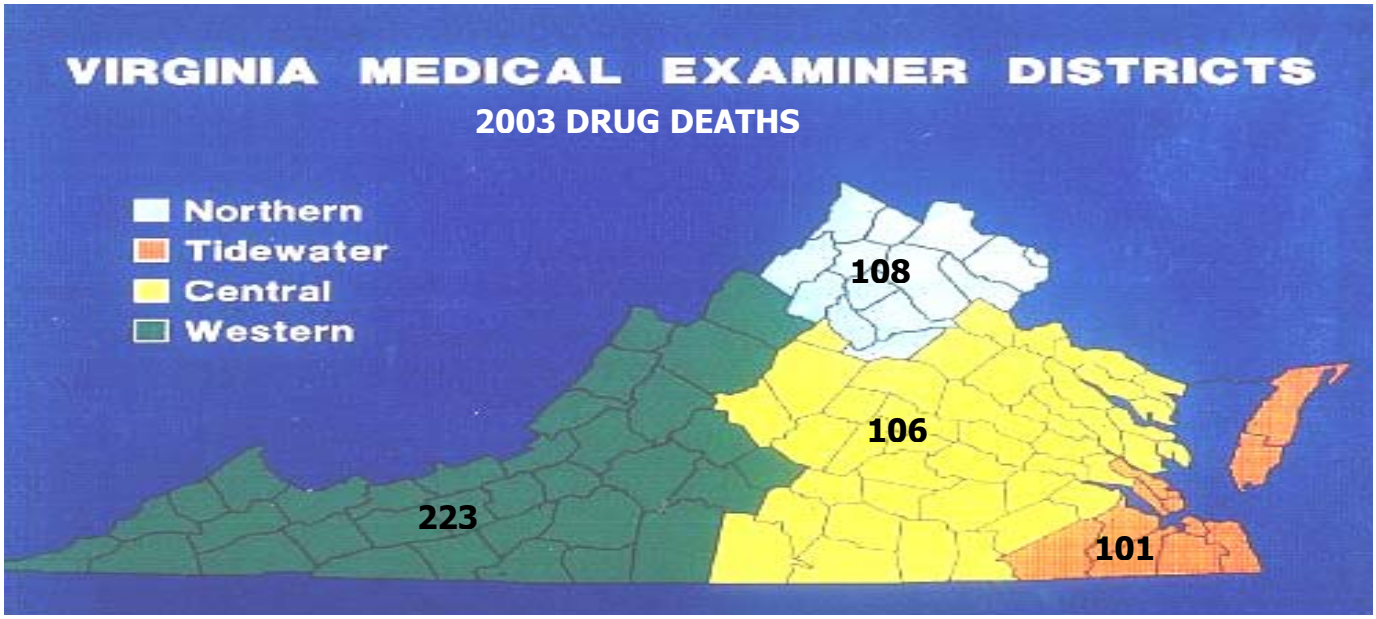
Note: This is not methadone used for or at Methadone Treatment Centers.

The amount of oxycodone (SCHEDULE II), methadone (SCHEDULE II) and hydrocodone (SCHEDULE III) distributed to Virginia has been increasing since 1998. Population growth and increased prescription drug insurance coverage may have been factors resulting in this increase. Pain management initiatives designed to raise awareness of the appropriate treatment of pain may partially explain the increase as well. Some of the increase may be attributed to the diversion and/or abuse of these products. The growth in oxycodone numbers could be attributed in part to the introduction and heavy marketing of OxyContin, an innovative sustained-release oxycodone product.

The increase in the distribution of these drugs is cause for concern. The Drug Abuse Warning Network (DAWN) January 2003 report, which is a report of drugs reported in overdoses from hospital emergency rooms stated that nationwide, in 2001, hydrocodone led the list of narcotic analgesics in ER overdoses with 21,567 mentions followed by oxycodone with 18,409. Similarly, DEA has continually reported that hydrocodone-containing products have much higher diversion rates than those containing oxycodone. Methadone is listed as #11 on the list of the top 20 mentions in ER overdoses with 11,709 mentions.

Office of the Medical Examiner:

Figure 5

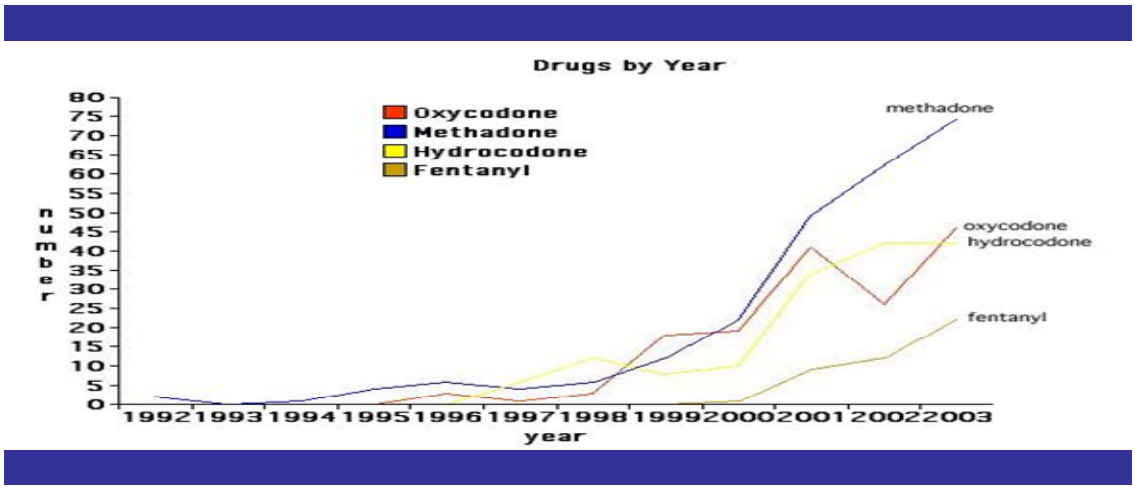


Drug deaths due to the abuse of prescription drugs occur throughout the Commonwealth but are concentrated in western Virginia. The most commonly named drugs as causes of death are methadone (SCHEDULE II), oxycodone (SCHEDULE II), hydrocodone (SCHEDULE III) and fentanyl (SCHEDULE II). It is common that these drugs are usually found in conjunction with other drugs. For instance, drugs commonly found with methadone fatal cases include: Alprazolam (SCHEDULE IV),

hydrocodone (SCHEDULE III), fentanyl (SCHEDULE II), carisoprodol (SCHEDULE VI), and oxycodone (SCHEDULE II).

Figure 6

Drug Deaths by Year

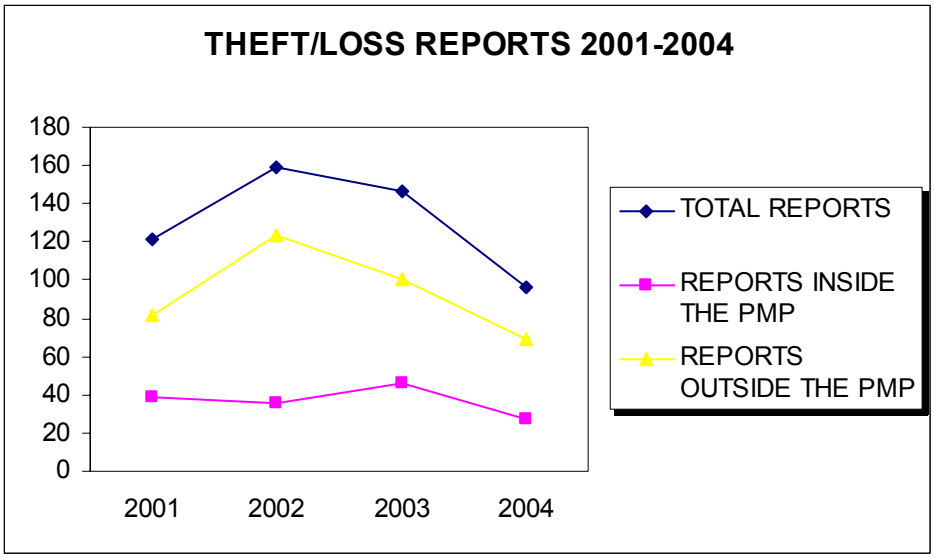


Note: Western District data.

In 1999, drug deaths in western Virginia caused by oxycodone were the most prevalent controlled substance cited as cause of death. By 2000, methadone had surpassed oxycodone and continues to be the drug most cited in these deaths. Hydrocodone, a Schedule III controlled substance surpassed oxycodone as the drug cited in cause of death in 2002. After a sharp decline in drug deaths due to oxycodone in 2002, the rate increased to surpass the 2001 levels in 2003.

Theft/Loss Reports:

Figure 7

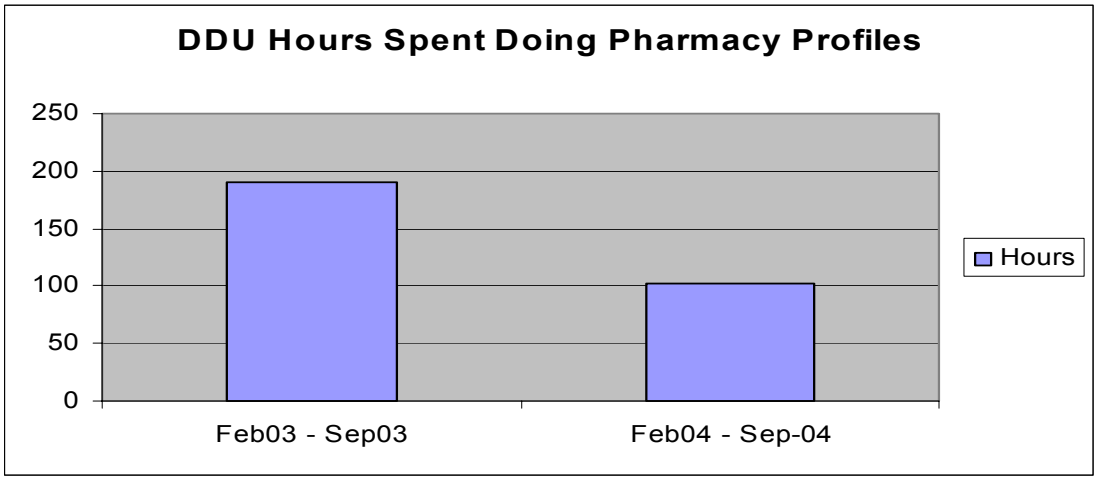


Note: 2004 data is for the time period of January 1, 2004 through September 30, 2004.

Pharmacies and other licensees are required to report to the Board of Pharmacy when a theft or unusual loss of controlled substances has occurred in their facility. They must also categorize the loss or unusual occurrence into 1 of 5 categories; employee pilferage, armed robbery, night break-in, other and lost-in-transit. The number one reported reason for a loss is employee pilferage. Data shows that there was an increase of night break-ins inside the program area in 2003. This trend is reversed so far in 2004. While no armed robberies were reported in 2002 or 2003, 4 have been reported so far in 2004 inside the program area.

Drug Diversion Unit:

Figure 8



Note: Data is from the program area only.

Figure 9

Time Period	Complaints	Investigations	Charges	Arrests
Feb03-Sep03 Virginia	538	290	226	180
Feb03-Sep03 PMP Area	178	111	122	22
Feb04-Sep04 Virginia	724	303	438	279
Feb04-Sep04 PMP Area	95	65	92	32

Investigators from the Drug Diversion Unit of the State Police began requesting data from the program in February 2003. In order to make a request for information from the program there must be an open investigation on a specific recipient, prescriber, or dispenser. Access to this type of information has been available to agents of the State Police for over 20 years. Use of the program streamlines the process of conducting the investigation of a complaint. In the past, once an investigation was opened an investigator would have to physically visit a number of pharmacies and manually review records to determine if there were prescriptions related to their investigation. This is quite time consuming. By

using the program, the investigator knows which pharmacies from which to requests records to use as evidence. This has resulted in a 53% decrease in hours spent performing pharmacy profiles during the covered time period. Investigators have commented that even more substantial savings could be realized if the program was statewide and expanded to cover controlled substances in Schedules II-IV. Although the number of arrests cannot be tied directly to the program there was a 31% increase in the number of arrests made during the same time period. This increase in the number of arrests is combined with a decrease in the number of investigations opened, from 111 in the 2003 time period to 65 in 2004.

Survey:

The Survey and Evaluation Research Laboratory of Virginia Commonwealth University released a survey in August 2004 on the prescription monitoring program. The survey was sponsored by the American Cancer Society (ACS), the South Atlantic chapter of the ACS in collaboration with the Virginia Cancer Pain Initiative. There were 7 basic areas that were surveyed: awareness of the program, general practice with regard to prescribing Schedule II drugs, querying the prescription database, access to the database, perceived oversight as a result of the program, usefulness of the program and familiarity with the Virginia Board of Medicine's Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain.

The overall response rate for the survey was 41% or 275 surveys returned out of 672. Of these, 48% of respondents had not heard of the program and returned the survey at that point leaving a survey group of 132 practitioners. Of this final group 36% reported prescribing fewer Schedule II prescriptions over the last 3 years. Of this subgroup, 89% cited intense media coverage or increased law enforcement activity as the reason for prescribing fewer Schedule II prescriptions. The report does not give numbers for any other category.

Only 11% of respondents reported having requested information from the program which is higher than the overall percentage of prescribers in the program area (1-2%) using the database. A majority of these respondents reported receiving the requested information within 1 to 3 days of submitting their requests. The 116 prescribers who had not queried the system were asked the reasons why they had not used the program. 40% reported not knowing about this feature of the program, 25% viewed it as unnecessary, 18% stated that the information was not available instantaneously, 17% stated that the paperwork was too time consuming and 9% stated that patients were not willing to give consent or the patients were suspicious.

When asked whether their prescribing behavior was being more closely monitored by law enforcement or regulatory agencies as a result of the program, 58% of respondents answered yes. Of

interest in this group is that 69% reported that this did not impact their ability to help patients manage their pain, 8% reported a positive impact, while 23% reported a negative impact.

Prescribers were asked about the usefulness of the program. 68% reported that the program was useful for monitoring patient's prescription histories and for decreasing the incidence of "doctor-shopping."

The Virginia Board of Medicine has had guidelines on the prescribing of opioids for the management of chronic, noncancer pain since 1996. However, 52% of respondents were not aware of the existence of these guidelines. Of the prescribers that were aware of the guidelines, 71% reported using them when making treatment decisions for their patients.

The recommendations based on the results of the survey revolve on providing education and information on the program and the benefits of using the program, as well as the prescribing guidelines from the Virginia Board of Medicine. The program has submitted articles for publication in various professional journals and has made presentations to various groups in Southwest Virginia. Additionally, the program held a conference in October 2004 and invited various stakeholders and interested parties. The conference covered subjects such as what the current prescription monitoring program consists of, effects of prescription drug abuse, talks from an addiction medicine specialist and a pain management specialist, information from 2 states that currently have prescription monitoring programs and a presentation on recommendations of the Advisory Committee for the program. The program realizes that education efforts must continue and is looking for more effective ways to provide information.

Recommendations

The Advisory Committee of the Prescription Monitoring Program identified several issues to be considered as a result of the evaluation workplan. The first question is continuation of the program. The program was developed as a pilot and under current law will expire after 2 years in 2005. If the General Assembly takes no action on the program, it will cease operations at the end of July 2005 when the federal grant for the program expires. The committee feels that there is a strong need for a comprehensive program in the Commonwealth of Virginia and presents the following recommendations.

The problem of prescription drug abuse is not limited to the southwest region of Virginia. For instance, just in the last month, there were news reports highlighting the abuse of OxyContin and methylphenidate in two different school systems in the Tri-Cities area of central Virginia. Doctor shoppers know where the boundary lines for the program are and will try to obtain their controlled substances where there is the least threat of being caught. The committee recommends expanding the program to cover all of Virginia and to require licensed out-of-state pharmacies to report the dispensing of covered substances to the program.

As a result of the evaluation of the program it has become clear that while Schedule II controlled substances have the greatest potential for abuse, illegal diversion occurs with greater frequency in other Schedules. The DEA has reported that hydrocodone containing products, classified in Schedule III, are the most commonly diverted controlled substances across the United States. Furthermore, benzodiazepines, classified in Schedule IV, are often found being abused in combination with other products in Schedules II and III. Since dispensers are already reporting the dispensing of Schedule II controlled substances, there should not be any additional burden on them if the Schedules are expanded. The committee recommends expanding the schedules of covered controlled substances to include Schedules II-IV.

Pharmacists have an obligation to dispense prescriptions only for an appropriate medical purpose. While pharmacists are required to report the dispensing of covered substances to the program they do not have access to the information. The committee recommends extending to pharmacists the authority to access information from the program as a tool to assist in determining the validity of a prescription for their patients.

Department of Health Professions personnel have existing authority in law to access records belonging to a specific person if that person is the subject of an investigation. However, the existing statute for the program did not include access to the program for this purpose. Personnel from the Health Practitioners Intervention Program (HPIP), as agents of the department would also benefit by being able to use the program as a monitoring tool. The committee recommends to extend access to department

investigative personnel and to allow access for designated HPIP personnel to the program on a specific licensee, registrant or certificate holder.

Medical examiners would benefit from having access to the program to assist in determining the cause of death in suspected drug death cases. Currently it is difficult to determine how a person may have received a controlled substance, having access to the program may make the determination of the cause of death more accurate. The committee recommends that medical examiners have access to the program in accordance with §32.1-287 of the Code of Virginia.

Currently a prescriber must be licensed by an appropriate regulatory board in the Commonwealth of Virginia in order to access the program. Because doctor shoppers know where the boundaries of programs such as Virginia's are, they will cross state lines in order to illegally obtain controlled substances. The committee recommends allowing a prescriber licensed in another state to request information on their patients from the program to assist in determining treatment history and making treatment decisions.

The current statute allows access to the program for use in Medicaid fraud investigations for dispensers, prescribers and recipients but stipulates the information may only be provided to the Medicaid Fraud Unit of the Office of the Attorney General. This office does not investigate recipient fraud only provider fraud. The committee recommends adding access to the Department of Medical Assistance Services.

The DEA, by law, has the authority to access information from prescribers and dispensers that they register. This is similar to the authority of the state police and department investigative personnel. However, agents of the DEA do not have access to information held by the program. The committee recommends adding access to authorized DEA agents, where requests would be limited to a DEA registrant named in an opened investigation.

Several states with prescription monitoring programs allow access to the information for statistical, research or educational purposes. This information may be invaluable when trying to identify abuse trends or the effectiveness of intervention programs. The committee recommends allowing the Director the discretion to provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients and/or persons who received prescriptions from dispensers.

The latest trend in prescription monitoring programs is to analyze the data in the program's possession to identify activity that may constitute doctor shopping or an abuse problem and make intervention the primary focus. Reports developed from this analysis are sent to the various prescribers and dispensers in an effort to deter this activity with interventions and treatment as the optimum outcome.

One state that initiated this type of program used a task force to determine exception thresholds and adjust them to ensure that patients with legitimate medical needs would not be targeted. Additionally, promoting intervention and treatment may result in substantial savings over the costs of incarceration. A 1997 study by Norman Hoffman of Brown University comparing the cost of drug treatment with the cost of incarceration found the cost ranging from $2,000 a year for outpatient treatment to $26,000 a year for incarceration. The committee recommends, in concept, for the program to provide patient information to individual practitioners, with proper oversight, information on specific patients targeting potential problems such as multiple prescriptions, multiple prescribers and pharmacies to aid in the proper treatment of patients.

The committee has considered allowing the analysis of data held by the program for the purpose of making referrals to regulatory agencies and law enforcement. It is clear that receiving such a referral from the program would just be the beginning of an investigation; it would not and could not be the basis for making charges. The committee has asked for more information on this topic, specifically on how other states may be doing this, the criteria being used, and the safeguards that are in place.

There are 2 other access issues that the program has become aware of, but have not been considered by the committee. The first is allowing access to authorized agents investigating fraud in Worker's Compensation cases. The second is allowing authorized personnel representing Drug Courts to have access to assist in monitoring compliance with sentencing requirements.

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APPENDIX A

Department of Health Professions

2005 Session of the General Assembly

Draft Legislation

Department of Health Professions

2005 Session of the General Assembly

Draft Legislation

A bill to amend the Code of Virginia by amending and reenacting §§54.1-2519, 54.1-2520, 54.1-2521, 54.1-2522, 54.1-2523, 54.1-2524, 54.1-2525,and 54.1-3434.1 and by adding §54.1-2523.1, relating to the Prescription Monitoring Program.

Be it enacted by the General Assembly of Virginia:

1. That §§54.1-2519, 54.1-2520, 54.1-2521, 54.1-2522, 54.1-2523, 54.1-2524, 54.1-2525,and 54.1-3434.1 of the Code of Virginia are amended and §54.1-2523.1 is added as follows:

§ 54.1-2519. ~~(For effective date, see note)~~ Definitions.

As used in this article, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means a controlled substance that is required to be reported to the Prescription Monitoring Program, pursuant to this chapter.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408<u>, or licensed in another state,</u> to issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2520. ~~(For effective date, see note)~~ Program establishment; Director's regulatory authority.

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, III and IV controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.).

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall establish an advisory committee within the department to assist in the implementation and evaluation of the Prescription Monitoring Program.

§ 54.1-2521. ~~(For effective date, see note)~~ Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number.
7. The dispenser's identifier number.
8. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

C. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2522. ~~(For effective date, see note)~~ Reporting exemptions.

The dispensing of covered substances under the following circumstances shall be exempt from the reporting requirements set forth in § 54.1-2521:

1. Dispensing of manufacturers' samples of such covered substances or of covered substances dispensed pursuant to an indigent patient program offered by a pharmaceutical manufacturer.
2. Dispensing of covered substances by a practitioner of the healing arts to his patient in a bona fide medical emergency or when pharmaceutical services are not available.
3. Administering of covered substances.

4. Dispensing of covered substances within an appropriately licensed narcotic maintenance treatment program.
5. Dispensing of covered substances to inpatients in hospitals or nursing facilities licensed by the Board of Health or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the Commonwealth.
6. Dispensing of covered substances to inpatients in hospices licensed by the Board of Health.
7. Dispensing of covered substances by veterinarians to animals within the usual course of their professional practice.
8. Dispensing of covered substances as otherwise provided in the Department's regulations.

§ 54.1-2523. ~~(For effective date, see note)~~ Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision A 79 of § 2.2-3705. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.
B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:
1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.
2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific ~~dispenser or prescriber~~ person licensed, certified, or registered by a health regulatory board or an applicant thereof, or information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions or to designated persons operating the Health Practitioners' Intervention Program pursuant to §54.1-2516.
3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.
4. Information relevant to a specific investigation of a specific dispenser or prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.
C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:
1. Information in the possession of the program concerning a recipient who is over the age of eighteen to that recipient.
2. Information on a specific recipient to a prescriber ~~licensed by the appropriate regulatory board in the Commonwealth~~ for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient, and the prescriber has obtained written consent to such disclosure from the recipient.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from that dispenser or the facility where that dispenser practices. Dispensers shall provide patients notice, in a manner specified by the Director in regulation, that such information may be requested from the Prescription Monitoring Program.

~~3~~ 4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

~~4~~ 5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services.

6. Information relevant to determination of cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information to qualified personnel for purposes of bona fide research or education provided data elements which would reasonably allow identification of a specific recipient, prescriber, or dispenser are deleted from information disclosed. Such release shall be made pursuant to a written agreement to ensure compliance with this section.

D. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

E. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

§ 54.1-2523.1. Discretionary disclosure for the purpose of intervention.

In addition to discretionary disclosure of information as provided in § 54.1-2523, the Director may disclose information using criteria that indicates possible misuse of covered substances by recipients to their specific prescribers for the purpose of intervention to prevent such misuse. Such information shall be made available through an analysis of data using criteria for indicators of misuse that have been developed by the Director in consultation with an advisory panel.

§ 54.1-2524. ~~(For effective date, see note)~~ Immunity from liability.

A. The Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Department pursuant to this chapter.

Further, the Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any

information in compliance with subsections B and C of § 54.1-2523 and the Department's regulations.
B. In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this chapter shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

§ 54.1-2525. ~~(For effective date, see note)~~ Unlawful disclosure of information; disciplinary action authorized; penalties.

A. It shall be unlawful for any person having access to the confidential information in the possession of the Program or any data or reports produced by the program to disclose such confidential information except as provided in this chapter. Any person having access to the confidential information in the possession of the program or any data or reports produced by the program who discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.
B. It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who lawfully receives information from the Prescription Monitoring Program and discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.
C. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside this Commonwealth which ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into this Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, and shall disclose to the Board all of the following:
1. The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs or devices to residents of this Commonwealth. A report containing this information shall be made on an annual basis and within thirty days after any change of office, corporate officer, or principal pharmacist.
2. That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the Commonwealth in which it is licensed as well as with all requests for information made by the Board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
3. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in this Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

4. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone service to facilitate communication between patients in this Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this Commonwealth.

C. Any pharmacy subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

~~C~~ D. The registration fee shall be the fee specified for pharmacies within Virginia.

2. That the Director of the Department of Health Professions shall promulgate regulations to implement provisions of this act within 280 days of enactment.

3. That provisions of this act shall become effective on the date of regulations become effective. The Director shall notify all dispensers subject to reporting requirements prior to the effective date.

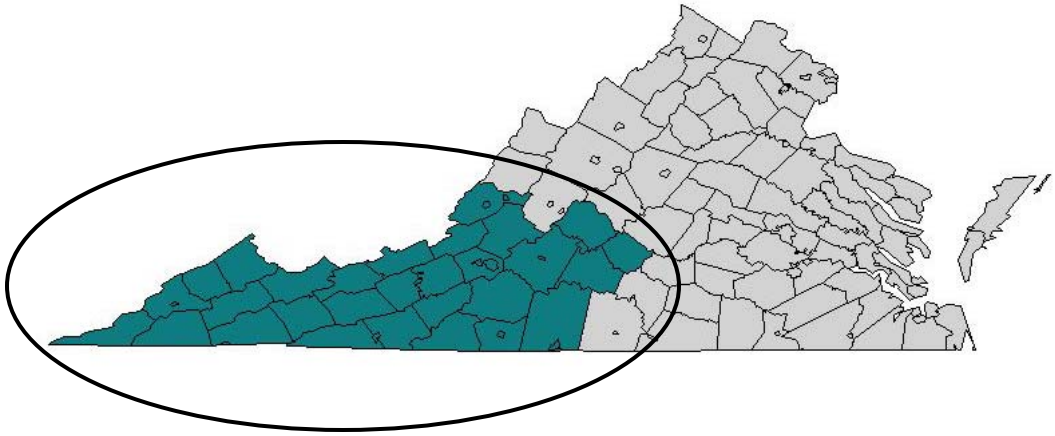
4. That the fourth and fifth enactments of Chapter 481 of the 2002 Acts of the Assembly are repealed.

APPENDIX B

Prescription Monitoring Program Survey: Report of Findings

PRESCRIPTION MONITORING PROGRAM SURVEY:

REPORT OF FINDINGS



August 2004

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EXECUTIVE SUMMARY

The Virginia General Assembly, in 2002, passed a law establishing a pilot prescription monitoring program (PMP) in State Health Planning Region III in Southwest Virginia. The PMP collects prescription data for schedule II drugs and maintains it in a central database. The database can be queried by physicians interested in examining a patient's pattern of schedule II drug use. The assumption is that the PMP will help deter the illegitimate use of schedule II drugs by helping physicians identify patients who are "doctor shopping".

The American Cancer Society (ACS) and the South Atlantic chapter of the ACS, in collaboration with the Virginia Cancer Pain Initiative, contracted with the Survey and Evaluation Research Laboratory (SERL) at Virginia Commonwealth University to collect information from physicians about their knowledge of, attitudes toward, and prescribing behaviors as a result of Virginia's PMP. The *Prescription Monitoring Program Survey* (*PMP Survey*) was mailed to 689 physicians in southwest Virginia, the pilot area for the PMP.

A total of 275 surveys were received yielding a response rate of 41%.[1] The findings will be used to gauge the impact of the PMP on the ability of physicians to help their patients manage pain. Also, the Virginia Department of Health Professions will find the information useful as they evaluate the pilot PMP program which they have been responsible for implementing in southwest Virginia.

Awareness of the PMP

- Slightly less than one-half of physicians reported having heard about the PMP prior to receiving the *PMP Survey.* [2] Of those who had heard of the PMP, slightly more than one-half acknowledged that they did not know what year it actually began. Only 39% correctly identified 2003 as the year the PMP began.

General Practice with Regard to Prescribing Schedule II Drugs

- Physicians were asked if, in the past three years, they have been prescribing fewer schedule II drugs. Thirty-six percent (n=46) of physicians responded affirmatively. Intense media coverage and increased law enforcement activity were cited most frequently as reasons for prescribing fewer schedule II drugs. Thirty-one percent (n=14) reported that prescribing fewer schedule II drugs had a negative impact on their ability to help their patients manage their pain; 60% reported no impact (n=27).

Querying the Prescription Database

- Only 11% of physicians (n=14) reported that they had requested information from the Virginia Department of Health Professions about a patient's prescription history. The majority of those requesting information received it within one to three days.

- Common reasons cited for not querying the PMP database were a lack of knowledge about the ability to request information, information not viewed as necessary, and an inability to access information instantaneously.

[1] Total valid sample was 672.
[2] Respondents who had heard about the PMP (n=132), continued the survey. Those who had not heard of the PMP were asked to end the survey and return it to SERL in the envelope provided.

Access to the PMP Database

- The vast majority of physicians, 83%, felt that pharmacists should be able to request information about patients' prescription histories (n=106). Only 17% did not (n=22).

Perceived Oversight as a Result of the PMP

- Nearly 60% of physicians believe that their prescribing behaviors are being monitored more closely as a result of the PMP. Of the 75 who perceived an increase in monitoring, 23% reported that this has had a negative impact on their ability to help their patients manage their pain, 8% reported a positive impact, and 69% reported no impact at all.

Usefulness of the PMP

- Despite low utilization of the PMP database, 68% of physicians reported that the PMP was useful for monitoring patients' prescription histories with regard to schedule II drugs; 24% did not know if it was useful for this purpose. The results were essentially the same with regard to the usefulness of the program for decreasing the incidence of "doctor shopping".

Familiarity with Virginia Board of Medicine's Guidelines

- Of the 131 respondents, 48% (n=63) were aware of the Virginia Board of Medicine's *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain* and 52% (n=68) were not. Of those who were aware of the *Guidelines*, 71% reported using them when making decisions about pain treatment for their patients (n=42).

Recommendations

The *PMP Survey* yielded interesting findings that can be used to inform programmatic and policy decisions with regard to the PMP. Based on the findings, the following recommendations are made:

1. Ongoing education campaigns are needed to make physicians fully aware of the PMP and its purpose. These efforts should attempt to dissuade the perception that the PMP is a mechanism to more closely monitor physician prescribing behaviors.
2. Physicians need to receive ongoing information about the PMP database and ways in which the database can be used as part of their clinical practice.
3. Explore benefits and drawbacks to allowing pharmacists to access the PMP database.
4. Provide physicians with a copy of the *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain*.
5. Of physicians believing they are being monitored more closely, nearly one-quarter reported that this had a negative impact on their ability to help patients manage their pain. Further study is warranted to explore this unintended consequence of the PMP.

INTRODUCTION

The Virginia General Assembly, in 2002, passed a law establishing a pilot prescription monitoring program (PMP) in State Health Planning Region III in Southwest Virginia. The PMP collects prescription data for schedule II drugs and maintains it in a central database. The database can be queried by physicians interested in examining a patient's pattern of schedule II drug use. The assumption is that the PMP will help deter the illegitimate use of schedule II drugs by helping physicians identify patients who are "doctor shopping".

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METHODS

Survey Development

The *PMP Survey* consisted of a number of close-ended questions focused on practice characteristics, awareness of the PMP, attitudes toward the PMP, and prescribing behaviors. Prior to administration, the *PMP Survey* was reviewed by leadership at the Virginia Department of Health Professions, the PMP Advisory Council, a few practicing physicians in southwest Virginia, and specialists in cancer care. Feedback was incorporated. In May 2004, a two-wave mailing was conducted with prenotification and reminder postcards. Also, in an effort to enhance response rates, a web-based option was made available. The final version of the *PMP Survey* can be found as Appendix A.

Study Population

Rather than drawing a sample, all physicians in State Health Planning Region III in Southwest Virginia practicing in one or more of the following specialties were surveyed: Internal Medicine, Family Practice, Neurology, and Orthopedics.[3,4] Physician mailing addresses were provided to SERL by the Virginia Department of Health Professions. A total of 689 physicians were surveyed.

Response Rate

Of the 689 surveys sent, 17 were deemed unusable[5], yielding a valid sample of 672. A total of 275 surveys were completed, 264 via the mail and 11 via the web. The overall response rate for the *PMP Survey* was 41%.

[3] The following counties / cities are located in State Health Planning Region III in Southwest Virginia: Bedford City, Alleghany, Grayson, Bristol City, Amherst, Henry, Clifton Forge City, Appomattox, Lee, Covington City, Bedford, Montgomery, Danville City, Bland, Patrick, Galax City, Botetourt, Pittsylvania, Lynchburg City, Buchanan, Pulaski, Martinsville City, Campbell, Roanoke, Norton City, Carroll, Russell, Radford City, Craig, Scott, Roanoke City, Dickenson, Smyth, Salem City, Floyd, Tazewell, Franklin, Washington, Giles, Wise, and Wythe. Physicians with mailing addresses in these localities were selected for survey participation because it is in this region that the PMP was piloted.

[4] At the time the PMP Survey was fielded, two additional physician-focused surveys were being conducted by SERL. In order to avoid having one physician participate in multiple surveys simultaneously, physicians participating in either of the other two surveys were removed from the PMP sample (n=168).

[5] Bad address, deceased, refused, or retired.

METHODS (con't)

Data Entry and Data Analysis

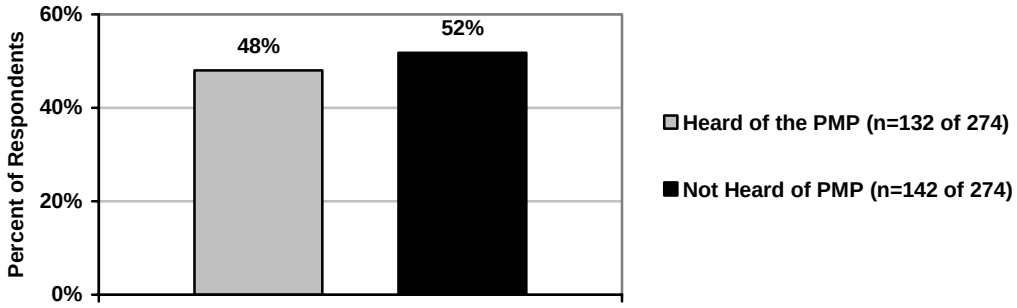
Data from individuals opting to complete the survey via the web were stored in the web survey database. Data from individuals opting to complete the mail survey were entered into the web survey database by SERL data entry staff. A flag was created to distinguish web completions from mail completions. Standard quality assurance activities occurred with all data entered by SERL staff.[6] SPSS 11.5 was used for all data analysis activities.

RESULTS

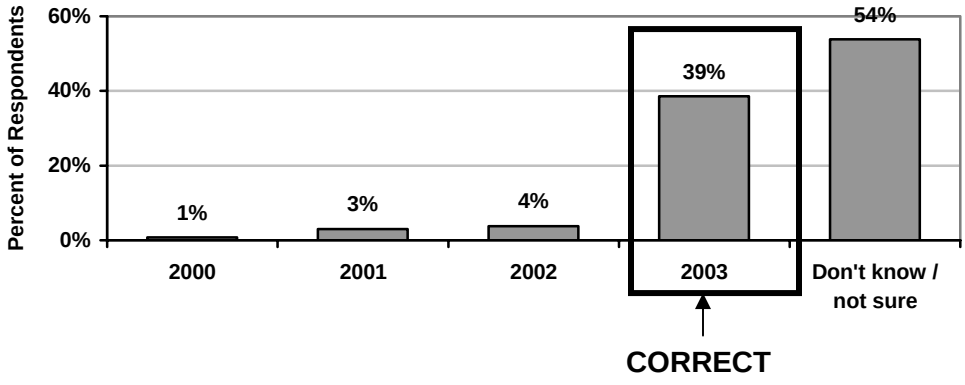
This section provides a summary of the results generated through analyses of the 275 completed *PMP Surveys* returned to SERL.

Awareness of the PMP

- Slightly less than one-half of physicians reported having heard about the PMP prior to receiving the *PMP Survey.* [7]



- Of those who had heard of the PMP, slightly more than one-half acknowledged that they did not know what year it actually began. Only 39% correctly identified 2003 as the year the PMP began.



[6] A mailroom supervisor verifies a minimum of 10% of all surveys entered. If any one individual's accuracy rate falls lower than 99.5% then 100% of the forms that individual entered are verified and corrected.

[7] Respondents who had heard about the PMP (n=132), continued the survey. Those who had not heard of the PMP were asked to end the survey and return it to SERL in the envelope provided.

Characteristics of Physicians Aware of the PMP

In terms of specialty…….

- 40% of the respondents were in family practice (n=52).
- 31% of the respondents were in internal medicine (n=41).
- The remainder of the physicians were in neurology (n=2), orthopedics (n=1), psychiatry (n=8), emergency medicine (n=12), or some other specialty (n=13).

In terms of practice……..

- Physicians, on average, saw 21 patients a day.
- Physicians, on average, had 20 years of experience in their profession.

General Practice with Regard to Prescribing Schedule II Drugs

Physicians were asked if, in the past three years, they have been prescribing fewer schedule II drugs.

- 36% of physicians reported prescribing fewer schedule II drugs (n=46).
    - Of these, 48% (n=22) reported intense media cover and 41% (n=19) reported increased law enforcement activity as reasons for prescribing fewer schedule II drugs.
    - 31% (n=14) reported that prescribing fewer schedule II drugs had a negative impact on their ability to help their patients manage their pain; 60% reported no impact (n=27).
    - 57% (n=26) reported that they were prescribing more schedule III and IV drugs as a result of prescribing fewer schedule II drugs.

Querying the Prescription Database

Physicians practicing in southwest Virginia are able to request information about their patient's prescription history with regard to schedule II drugs. To gain access to prescription information, written consent from the patient is required. Once written consent is obtained, the physician sends a written request for information to the Virginia Department of Health Professions.

- Only 11% of physicians (n=14) reported that they had requested information from the Virginia Department of Health Professions about a patient's prescription history.
    - 12 physicians requested information on an average of 4.3 patients within the past three months. Requests ranged from a low of one to a high of 12 with a median of 2.5.
    - All 12 physicians reported receiving information within seven days of submitting their request and the majority, 75%, reported receiving information within one to three days of submitting their request.

Querying the Prescription Database (con't)

- The 116 physicians who had not queried the database were asked why not. Common reasons cited by respondents included a lack of knowledge about the ability to request information, information not viewed as necessary, and an inability to access information instantaneously. The following table provides the reasons cited by physicians for not querying the PMP database.

REASON	N	%
Did not know about this aspect of the PMP	46	40%
Not viewed as necessary	29	25%
Information not available instantaneously	21	18%
Paperwork too time consuming	20	17%
Other*	12	10%
Patients not willing to consent or patients suspicious	11	9%
PMP does not cover schedules of interest	10	9%

Access to the PMP Database

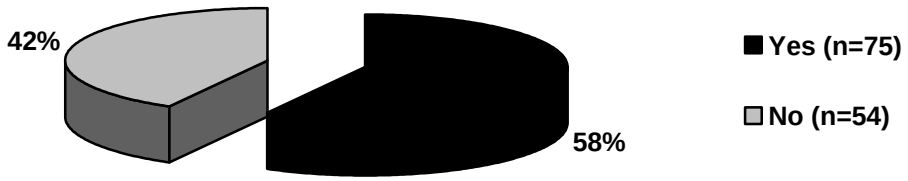
- The vast majority of physicians, 83%, felt that pharmacists should be able to request information about patients' prescription histories (n=106). Only 17% did not (n=22).

Perceived Oversight as a Result of the PMP

The primary purpose of the PMP is to help providers prospectively identify patients who may be "doctor shopping" in an effort to access schedule II drugs. An unintended consequence is that physicians may feel as if there is a greater oversight of their prescribing behaviors by law enforcement and/or regulatory agencies.

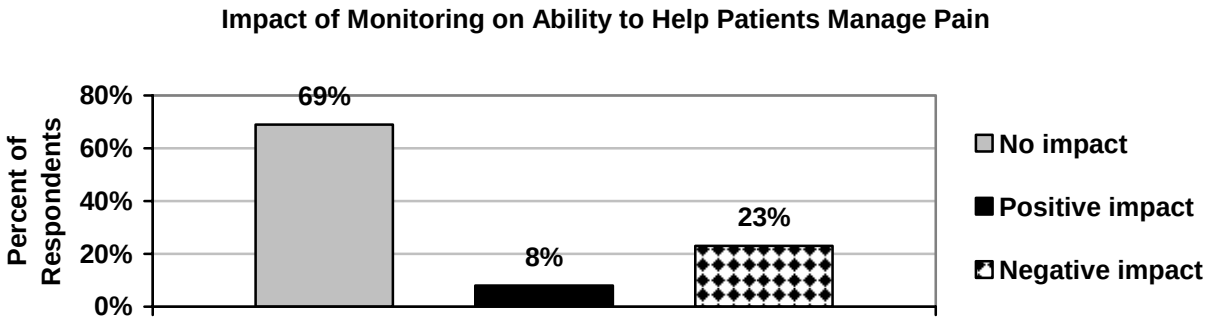
- As can be seen in the diagram below, nearly 60% believe that their prescribing behaviors are being monitored more closely.

As a result of the PMP, do you believe that your prescribing behavior is being monitored more closely by law enforcement or regulatory agencies?



Perceived Oversight as a Result of the PMP (con't)

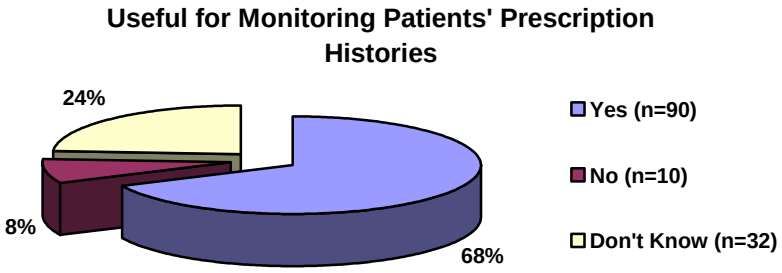
- Physicians were asked how increased oversight has impacted their ability to help patients manage their pain. Of the 75 who perceived an increase in monitoring, 23% reported that this has had a negative impact on their ability to help their patients manage their pain, 8% reported a positive impact, and 69% reported no impact at all.



Usefulness of the PMP

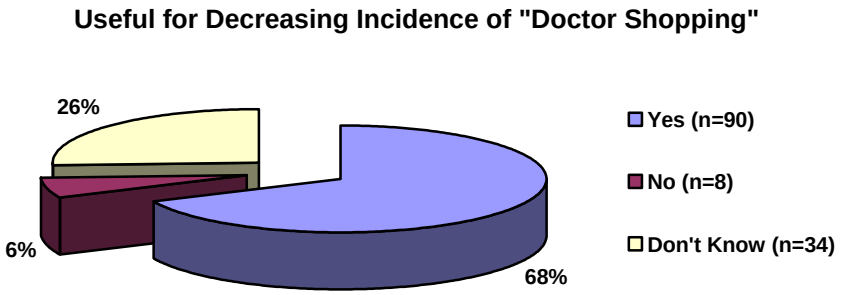
Physicians were asked if the PMP was useful for monitoring patients' prescription histories and if it was useful for decreasing the incidence of "doctor shopping" in order to access schedule II drugs.

- Despite low utilization of the PMP database, 68% of physicians reported that the PMP was useful for monitoring patients' prescription histories with regard to schedule II drugs; 24% did not know if it was useful for this purpose. The remaining 8% reported that it was not useful for this purpose.



Usefulness of the PMP (con't)

- The results were essentially the same with regard to the usefulness of the program for decreasing the incidence of "doctor shopping"; 68% reported that the program was useful and 26% did not know. The remaining 6% reported that the program was not useful for this purpose.

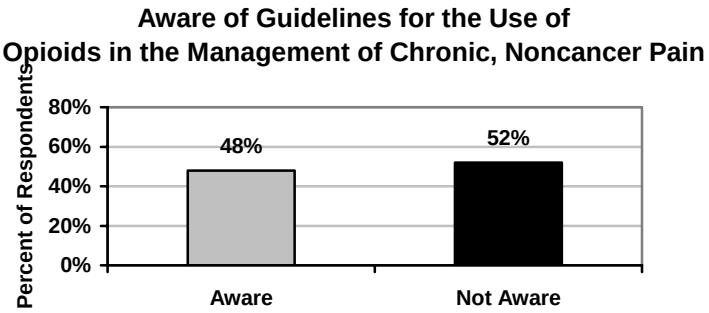


- Physicians who believe that the PMP is useful for monitoring prescription histories tend to also believe that the PMP is useful for decreasing the incidence of doctor shopping.

Familiarity with Virginia Board of Medicine's Guidelines

Physicians were asked if they were aware of the Virginia Board of Medicine's *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain*.

- Of the 131 respondents, 48% were aware (n=63) and 52% were not (n=68).



- Of those who were aware of the *Guidelines*, 71% reported using them when making decisions about pain treatment for their patients (n=42).

Recommendations

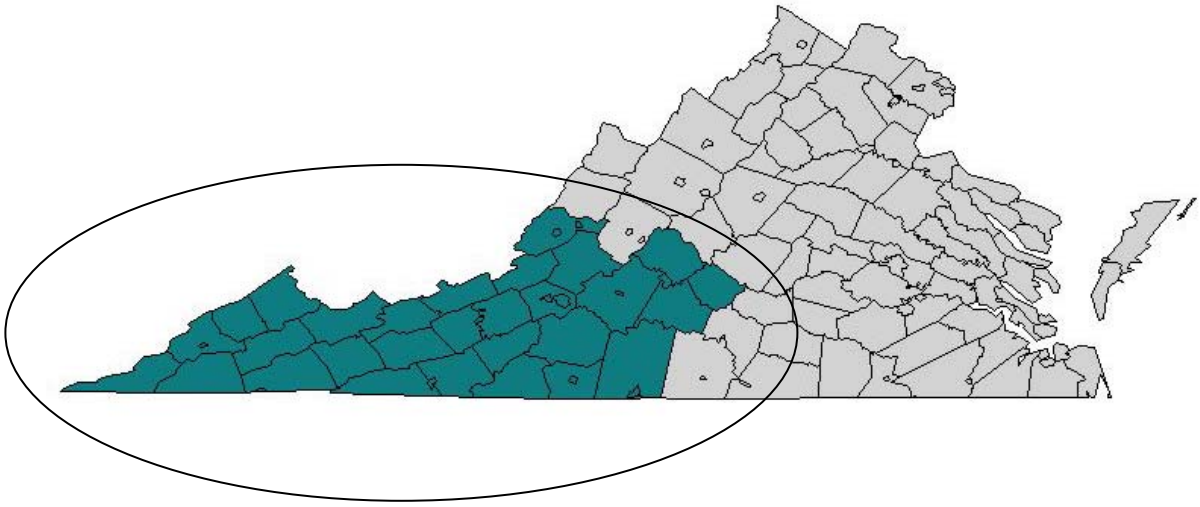
The *PMP Survey* yielded interesting findings that can be used to inform programmatic and policy decisions with regard to the PMP. Based on the findings, the following recommendations are made:

1. Ongoing education campaigns are needed to make physicians fully aware of the PMP and its purpose. These efforts should attempt to dissuade the perception that the PMP is a mechanism to more closely monitor physician prescribing behaviors.
2. Physicians need to receive ongoing information about the PMP database and ways in which the database can be used as part of their clinical practice.
3. Explore benefits and drawbacks to allowing pharmacists to access the PMP database.
4. Provide physicians with a copy of the *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain*.
5. Of physicians believing they are being monitored more closely, nearly one-quarter reported that this had a negative impact on their ability to help patients manage their pain. Further study is warranted to further explore this unintended consequence of the PMP.

Appendix A
PMP Survey

Code: _____

Prescription Monitoring Program Survey



SUMMER 2004

Virginia Commonwealth University
Survey and Evaluation Research Laboratory

Section I: Questions about Virginia's Prescription Monitoring Program (PMP)

1. Before receiving this survey, had you heard of Virginia's Prescription Monitoring Program (PMP)?

☐[1] Yes → Please continue.

☐[2] No → Thank you. Please return the survey in the enclosed envelope.

2. In what year did the PMP begin? *Check one only:*

☐[1] 1999 ☐[2] 2000 ☐[3] 2001 ☐[4] 2002 ☐[5] 2003 ☐[6] Don't know / not sure

3. The PMP allows physicians to request information from the Department of Health Professions about a patient's prescription history. Since the inception of the PMP, have you made any requests for patient information?

☐[1] Yes → Please go to next question.

☐[2] No →

What is the primary reason? *Check all that apply*:

☐[1] Patients not willing to consent / patients suspicious.
☐[2] Paperwork too time consuming.
☐[3] Did not know about this aspect of the PMP.
☐[4] Not viewed as necessary.
☐[5] PMP does not cover schedules of interest.
☐[6] Information not available instantaneously.
☐[7] Other: _____

→ Please go to question #6

4. How many patients have you requested information about in the past three (3) months?

Total number: _____ → Of all the requests made in the past three (3) months, in how many cases did the information you received alter your prescribing? _____ (# of cases)

5. On average, how long does it take to receive information about a patient after submitting a request to the Department of Health Professions? *Check one only:*

☐[1] 1 to 3 days ☐[2] 4 to 7 days ☐[3] 8 to 14 days ☐[4] More than 14 days

Section II: Impact of PMP on Practice

6. In the past three years, have you been prescribing fewer Schedule II controlled substances? *Check one only:*

☐[1] Yes → Go to question #6a, b, c.

☐[2] No → Go to question #7.

6a. What factors have resulted in you prescribing fewer Schedule II controlled substances? *Check all that apply:*

☐[1] Intense media coverage
☐[2] Enactment of the PMP
☐[3] Increased law enforcement activity
☐[4] Other_____

NEXT PAGE →

Section II: Impact of PMP on Practice (con't)

6b. Has prescribing fewer Schedule II controlled substances impacted your ability to help your patients manage their pain? *Check one only:*

☐[1] Yes, there has been a positive impact on my ability to help my patients manage their pain.
☐[2] Yes, there has been a negative impact on my ability to help my patients manage their pain.
☐[3] No, there has been no impact on my ability to help my patients manage their pain.

6c. As a result of prescribing fewer Schedule II controlled substances have you prescribed more schedule III and IV controlled substances? ☐[1] Yes ☐[2] No

7. As a result of the PMP, do you believe that your prescribing behaviors are being monitored more closely by law enforcement or regulatory agencies? *Check one only:*

☐[1] Yes → Go to question #7a.

☐[2] No → Go to question #8.

7a. Has this impacted your ability to help your patients manage their pain? *Check one only:*
☐[1] Yes, there has been a positive impact on my ability to help my patients manage their pain.
☐[2] Yes, there has been a negative impact on my ability to help my patients manage their pain.
☐[3] No, there has been no impact on my ability to help my patients manage pain.

8. Currently pharmacists are unable to request information about patients' prescription histories. Do you think that pharmacists should be able to request this information? *Check one only:* ☐[1] Yes ☐[2] No

Section III: Opinions about the PMP

9. Do you think the PMP is a useful program for monitoring patients' prescription histories with regard to schedule II controlled substances? ☐[1] Yes ☐[2] No ☐[3] Don't know

10. Do you think the PMP is a useful program for decreasing the incidence of "doctor shopping" in order to access schedule II controlled substances? ☐[1] Yes ☐[2] No ☐[3]Don't know

Section IV: Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain

11. Are you aware of the Virginia Board of Medicine's *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain*? *Check one only:* ☐[1] Yes ☐[2] No → Go to question #12

11a. If yes, do you use the *Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain* when making decisions about pain treatment for your patients? ☐[1] Yes ☐[2] No

Section V: Practice Information

12. In what city/county do you currently practice? _____
[If you practice in more than one city / county, please report the one that you spend the majority of your time in.]

13. What best describes your specialty? *Check one only:*

☐[1] Internal Medicine ☐[2] Family Practice ☐[3] Neurology ☐[4] Orthopedics ☐[5] Other: _____

14. On average, across all practice sites, how many patients do you see a day? _____(# of patients)
15. Total number of years in practice, including internship and residency: _____(# of years)

THANK YOU FOR COMPLETING THE SURVEY.
PLEASE RETURN IT USING THE ENCLOSED ENVELOPE AS SOON AS POSSIBLE.

Appendix C

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Adopted June 24, 2004

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.
2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA,* 274(20) (1995): p. 1591-1598.
3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will

consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and

state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Appendix D

Fact Sheets From the National Drug Control Strategy 2004

REDUCING PRESCRIPTION DRUG ABUSE

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995.

The President's National Drug Control Strategy engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription pshychotherapeutic drugs.

The Strategy focuses on three core tactics for reducing prescription drug abuse:

- ☑ Business outreach and consumer protection
- ☑ Investigation and enforcement against the illegal sale and diversion of prescription drugs
- ☑ Education and training of physicians and consumers

☑ Business Outreach and Consumer Protection: The Food and Drug Administration (FDA) will work to ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. Specific examples include labeling that properly identifies patients for whom these products are appropriate and that recommends a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

- ➢ FDA will consider Risk Management Programs (RiskMAPs) during the approval process for Schedule II opiate drug products. RiskMAPs help ensure the safe prescription and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.
- ➢ FDA, the Drug Enforcement Administration (DEA), and the White House Office of National Drug Control Policy will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy. Identification of persons at risk for opiate abuse and addiction will help their medical caretakers to more effectively monitor for signs of abuse.
- ➢ Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. Such businesses include credit card companies, shippers, and Internet Service Providers (ISP). These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require Internet pharmacies to display on their websites the physical street address of their primary business locations.

☑ Investigation and Enforcement: The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies – or "pill mills" – offer controlled substances and other prescriptions direct to consumers online. These unscrupulous entities are often foreign-based and undermine state licensing systems, exposing consumers to potentially counterfeit, adulterated, and contaminated products.

- ➢ The FDA's Office of Criminal Investigations (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

Investigation and Enforcement (continued):

- DEA will deploy sophisticated web crawler/data mining technology to generate investigative leads that could lead to enforcement actions against illegal pill mills.
- ONDCP and DEA will work with state officials to expand the number of Prescription Monitoring Programs (PMPs) and to facilitate information sharing among jurisdictions. Currently, 20 states have PMPs to identify individuals who attempt to fill multiple prescriptions from numerous doctors ("doctor shopping"). This information can help reputable physicians and pharmacies prevent illegal diversion of controlled substances.
- FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to do spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers.

☑ Education and Training: One potential means of preventing diversion and abuse of prescription drugs is wider dissemination of continuing medical education programs for physicians and other health professionals regarding pain management. These programs will seek to balance the legitimate needs of patients against the risk of diversion and abuse.

- The DEA, with support from the FDA, is working to consult with medical associations to identify existing best practices in physician training in the field of pain management. The agencies plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for physicians who prescribe controlled substances. The curriculum will educate doctors on the appropriate medical use of opioids as well as the risks of abuse and addiction.
- ONDCP, DEA, and FDA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

☑ Protecting Safe and Effective Use of Medications: Some estimate that more than 10 million Americans suffer from chronic pain. The efforts outlined in the National Drug Control Strategy to prevent and reduce the diversion and abuse of prescription drugs will help to ensure that patients have full and appropriate access to the medications that best meet their needs and that their healthcare providers are informed and trained to effectively manage pain while limiting potential for misuse, abuse, and addiction.

THE NATIONAL DRUG CONTROL STRATEGY

The President's National Drug Control Strategy for 2004 focuses on three core priorities: stopping use before it starts, healing America's drug users, and disrupting the market.

- The Strategy reports progress toward meeting the President's goals of reducing drug use by 10 percent over two years, and 25 percent over five years, highlighted by an 11 percent drop in drug use among young people, exceeding the two-year goal.
- The non-medical use of prescription drugs has emerged in the last decade as a major problem. The Strategy highlights the importance of prescription monitoring, and physician training, and education programs to curb the abuse of prescription drugs.
- The 2004 Strategy also highlights a $23 million funding increase to support schools in their design and implementation of student drug testing, assessment, referral, and intervention programs.

Key Points on the National Drug Control Strategy

☑ Progress Toward The President's Two- and Five-Year Goals: The Nation has exceeded the President's two-year goal with an 11 percent reduction in past-month use of any illicit drug by youth between 2001 and 2003, according to data from the Monitoring the Future study, an annual survey of the Nation's 8th, 10th, and 12th graders. This is the first decline in youth drug use of such a magnitude in more than a decade, and means that 400,000 fewer young people use drugs today than in 2001. Data indicating progress toward adult goals is not yet available, and will be measured from the baseline of the 2002 National Survey on Drug Use and Health.

The Strategy proposes a fiscal year 2005 budget of $12.6 billion for drug control serving three core priorities:

☑ Stopping Drug Use Before It Starts: Research shows that people who make it through their teenage years without using drugs are much less likely to start using later in life. In homes, schools, places of worship, the workplace, and civic, social, and athletic organizations, Americans must set standards that reaffirm the values of responsibility and good citizenship while rejecting the image of drug use as consistent with individual freedom. America's children must learn from an early age that rejecting drug use is an expectation and lifelong responsibility.

- The Strategy highlights the importance of student drug testing, a prevention approach that deters drug use while guiding users to needed treatment or counseling. In fiscal year 2005, the Administration requests $25 million for student drug testing programs.
- The President's fiscal year 2005 Budget continues funding for the ONDCP's National Youth Anti-Drug Media Campaign at $145 million. The Media Campaign's Early Intervention initiative, which was launched on Super Bowl Sunday, aims to reduce teen substance abuse by focusing on those closest to youth drug users. The initiative harnesses the power of peers and parents to intervene in the lives of young people who may be using drugs.
- The Administration proposes a $10.4 million increase in funding for the Drug-Free Communities Program. These additional resources will fund approximately 100 new local community anti-drug coalitions working to prevent substance abuse among young people.

☑ Healing America's Drug Users: Despite substantial drug prevention efforts, over 19 million Americans still use drugs on a monthly basis, and roughly seven million meet the clinical criteria for needing drug treatment. Yet the overwhelming majority of users in need of drug treatment fail to recognize the severity of their problem. The second core priority of the Strategy emphasizes the crucial need for family, friends, and former addicts to intercede with and support those fighting to overcome substance abuse. Drug users also need the support of institutions and the people who run them—employers, law enforcement agencies, faith-based and community organizations, and health care providers, among others—to help them recognize their drug addiction and to seek treatment.

FOR DETAILED DATA TABLES RELATED TO THE NATIONAL DRUG CONTROL STRATEGY, PLEASE VISIT WWW.WHITEHOUSEDRUGPOLICY.GOV

- Overall, for 2005, the Administration proposes $3.7 billion for drug treatment, an increase of 9.6 percent over 2004.
- The misuse of psychotherapeutic drugs—pain relievers, tranquilizers, stimulants, and sedatives—was the second leading category of illicit drug use in 2002, following marijuana. The Strategy recognizes the effectiveness of state prescription monitoring programs, and calls on the pharmaceutical industry, medical community, and state governments to become partners in the effort to fight the illegal sale, diversion, and use of prescription drugs in a manner that does not impede legitimate medical needs.
- The 2005 request includes $200 million (over two times what was enacted in 2004) for Access to Recovery—a treatment initiative to provide drug treatment to individuals otherwise unable to obtain access to services. People in need of treatment receive an assessment of their treatment need and are issued vouchers to obtain help at effective treatment organizations, including faith-based and community organizations.

☑ Disrupting the Market: The third priority of the Strategy seeks to capitalize on the engagement of producer and transit countries like Colombia and Mexico in order to address the drug trade as a business—one that faces numerous and often overlooked obstacles that may be used as pressure points. The drug trade is not an unstoppable force of nature but rather a profit-making enterprise that can be disrupted. Coupled with our efforts to reduce demand, every action that makes the drug trade more costly and less profitable works to "break" the market.

- To help secure America's borders, the President's budget includes $2.6 billion for drug interdiction, an increase of 4.5 percent from 2004. Internationally, the Administration will continue to target the supply of illegal drugs in the source countries.
- Colombia has seen significant reductions in cocaine and heroin production, due in large part to the efforts of Colombian President Alvaro Uribe. And unlike in past years, these reductions have not been offset by increased production by Colombia's neighbors. The Administration is requesting $731 million in dedicated funds in 2005 for the Andean Counterdrug Initiative to be applied in Colombia, Peru, Bolivia, Ecuador, Brazil, Venezuela, and Panama.
- The Strategy highlights the success of the Consolidated Priority Target list in the targeting and dismantling of major drug trafficking organizations.

National Drug Control Budget Summary

Drug Control Funding: Agency Summary

FY 2003–FY 2005 (Budget Authority in Millions)

	FY 2003 Final	FY 2004 Enacted	FY 2005 Request
Department of Defense	$905.9	$908.6	$852.7
Department of Education	644.0	624.5	611.0
Department of Health and Human Services			
National Institute on Drug Abuse	960.9	990.8	1,019.1
Substance Abuse and Mental Health Services Administration	2,354.3	2,488.7	2,637.7
Total HHS	3,315.2	3,479.5	3,656.8
Department of Homeland Security			
Immigration and Customs Enforcement	518.0	538.7	575.8
Customs and Border Protection	873.9	1,070.5	1,121.4
U.S. Coast Guard	648.1	773.7	822.3
Total DHS	2,040.0	2,382.9	2,519.4
Department of Justice			
Bureau of Prisons	43.2	47.7	49.3
Drug Enforcement Administration	1,639.8	1,703.0	1,815.7
Interagency Crime and Drug Enforcement [1]	477.2	550.6	580.6
Office of Justice Programs	269.6	181.3	304.3
Total Department of Justice	2,429.8	2,482.7	2,749.9
ONDCP			
Operations	26.3	27.8	27.6
High Intensity Drug Trafficking Area Program	226.0	225.0	208.4
Counterdrug Technology Assessment Center	46.5	41.8	40.0
Other Federal Drug Control Programs	221.8	227.6	235.0
Total ONDCP	520.6	522.2	511.0
Department of State			
Bureau of International Narcotics and Law Enforcement Affairs	874.3	914.4	921.6
Department of Veterans Affairs			
Veterans Health Administration	663.7	765.3	822.8
Other Presidential Priorities [2]	3.4	2.2	3.5
Total, Federal Drug Budget	$11,397.0	$12,082.3	$12,648.6

[1] Prior to FY 2004, funds for the Interagency Crime and Drug Enforcement programs were appropriated into two accounts, one in the Justice Department and one in the Treasury Department. Beginning in FY 2004 those accounts were consolidated. In this table funding is shown as combined for all three years.

[2] Includes the Small Business Administration's Drug Free Workplace grants and the National Highway Traffic Safety Administration's Drug Impaired Driving program.

Federal Drug Control Spending By Function
FY 2001–FY 2005
(Budget Authority in Millions)

	FY 2001 Final	FY 2002 Final	FY 2003 Final	FY 2004 Enacted	FY 2005 Request	FY 01 - FY 05 Change	
Function:							
Treatment (w/ Research)	$2,980.7	$3,092.4	$3,223.9	$3,392.1	$3,717.3	$736.6	21.7%
Percent	*30.3%*	*28.4%*	*28.3%*	*28.1%*	*29.4%*		
Prevention (w/ Research)	1,867.6	2,006.5	1,966.4	1,985.3	1,977.7	110.0	5.5%
Percent	*19.0%*	*18.4%*	*17.3%*	*16.4%*	*15.6%*		
Domestic Law Enforcement	2,462.8	2,794.7	2,954.1	3,080.5	3,201.1	738.2	24.0%
Percent	*25.1%*	*25.7%*	*25.9%*	*25.5%*	*25.3%*		
Interdiction	1,895.3	1,913.7	2,147.5	2,490.6	2,602.7	707.3	28.4%
Percent	*19.3%*	*17.6%*	*18.8%*	*20.6%*	*20.6%*		
International	617.3	1,084.5	1,105.1	1,133.9	1,149.9	532.6	47.0%
Percent	*6.3%*	*10.0%*	*9.7%*	*9.4%*	*9.1%*		
Total	**$9,823.8**	**$10,891.9**	**$11,397.0**	**$12,082.3**	**$12,648.6**	**$2,824.8**	**23.4%**
Supply/Demand Split:							
Supply	$4,975.5	$5,793.0	$6,206.7	$6,705.0	$6,953.7	$1,978.2	29.5%
Percent	*53.4%*	*53.2%*	*54.5%*	*55.5%*	*55.0%*		
Demand	4,848.3	5,098.9	5,190.3	5,377.3	5,694.9	846.6	15.7%
Percent	*46.6%*	*46.8%*	*45.5%*	*44.5%*	*45.0%*		
Total	**$9,823.8**	**$10,891.9**	**$11,397.0**	**$12,082.3**	**$12,648.6**	**$2,824.8**	**23.4%**

Appendix E

State of Nevada Prescription Controlled Substance Abuse Prevention Task Force 1997-2003

STATE OF NEVADA

Prescription Controlled Substance Abuse Prevention Task Force 1997-2003

Statutes and Regulations

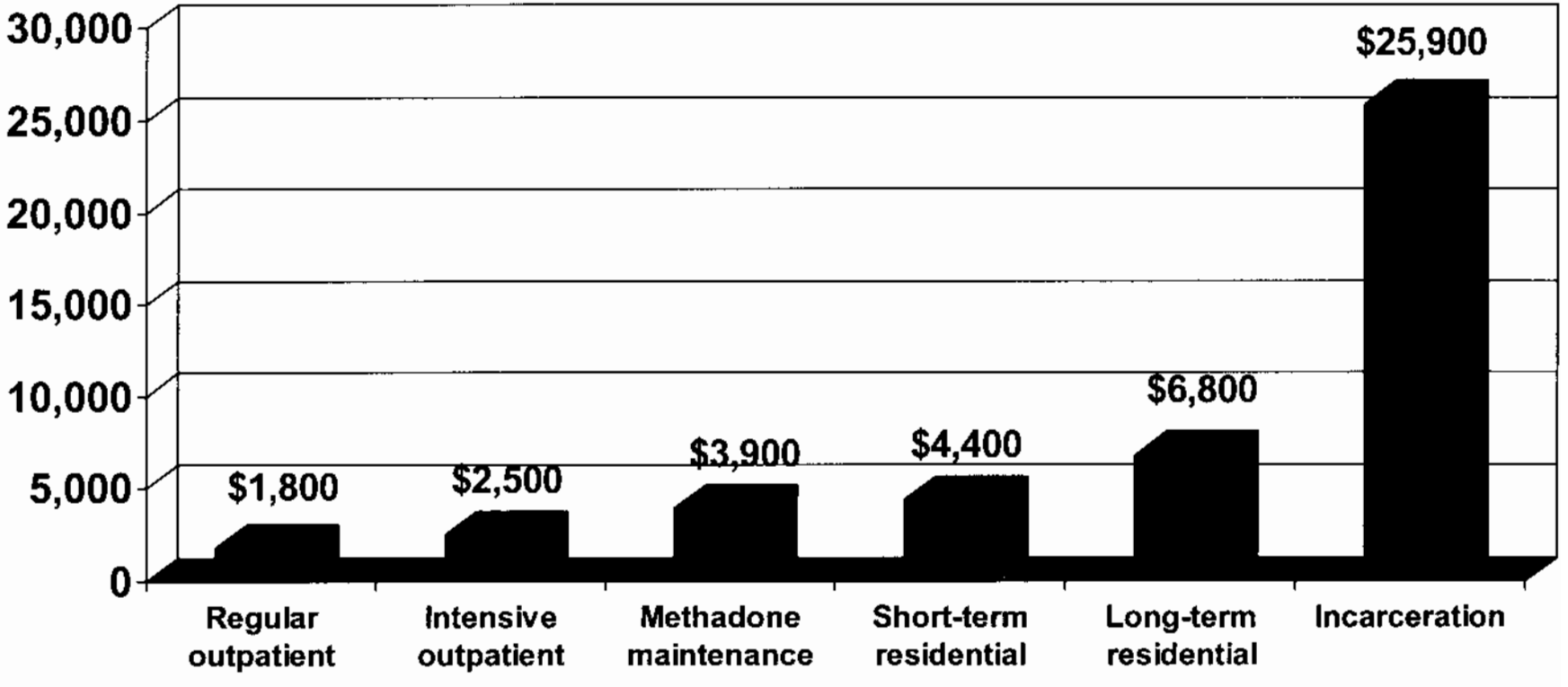
NRS 453.1545

- Intervention, NOT law enforcement
- Schedules 2, 3, and 4 controlled substances
- Multidisciplinary oversight (task force members)
- Limited access to information
- No interference with legitimate pain treatment
- Authorize acceptance of grants and gifts

NAC 639.926

- Mechanics of monthly reporting

COST OF DRUG TREATMENT - 1997

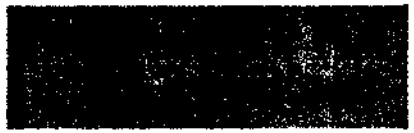


SOURCE: Norman Hoffman, Brown University AP

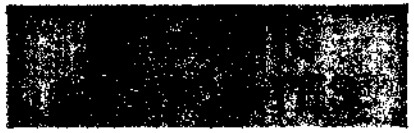
Cost to run program

1996 – 1997	$131,830.00 start-up year
1997 – 1998	$100,376,87
1998 – 1999	$ 90,084,05
1999 – 2000	$111,949,57
2000 – 2001	$ 91,640.37
2001 – 2002	$123,867.83
2002 – 2003	$143,430.42

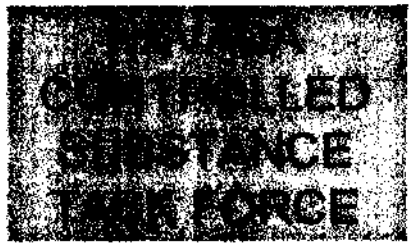
Data Collection Process



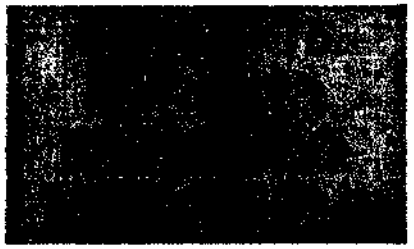
Pharmacies send data via modem or disk.



AA organizes and verifies data integrity.

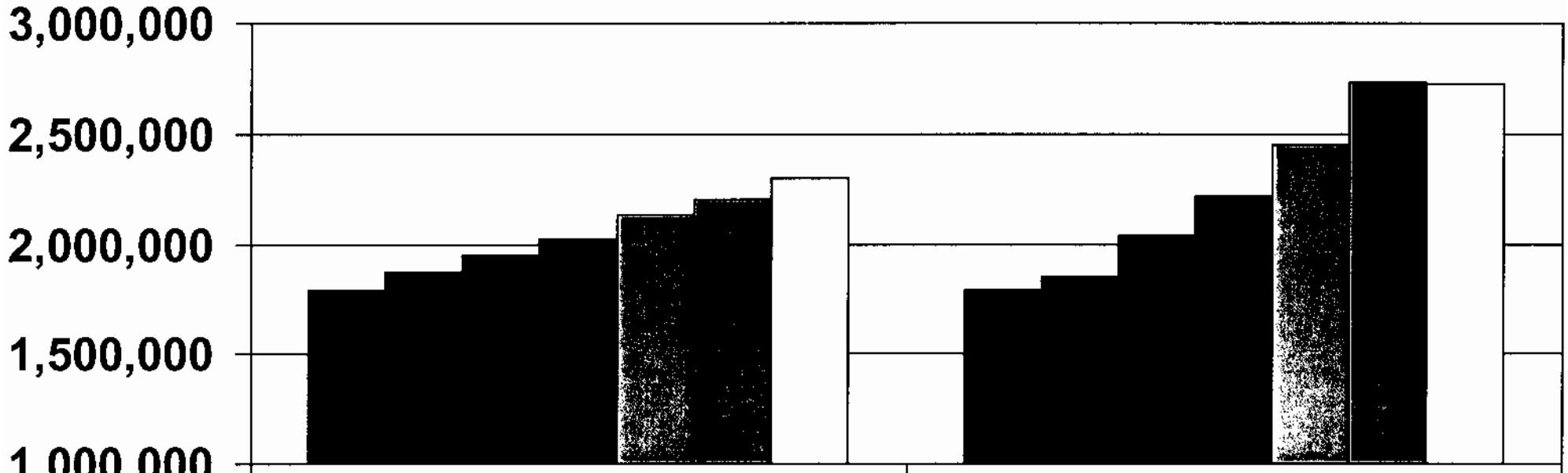


CSTF updates database, verifies & processes data.



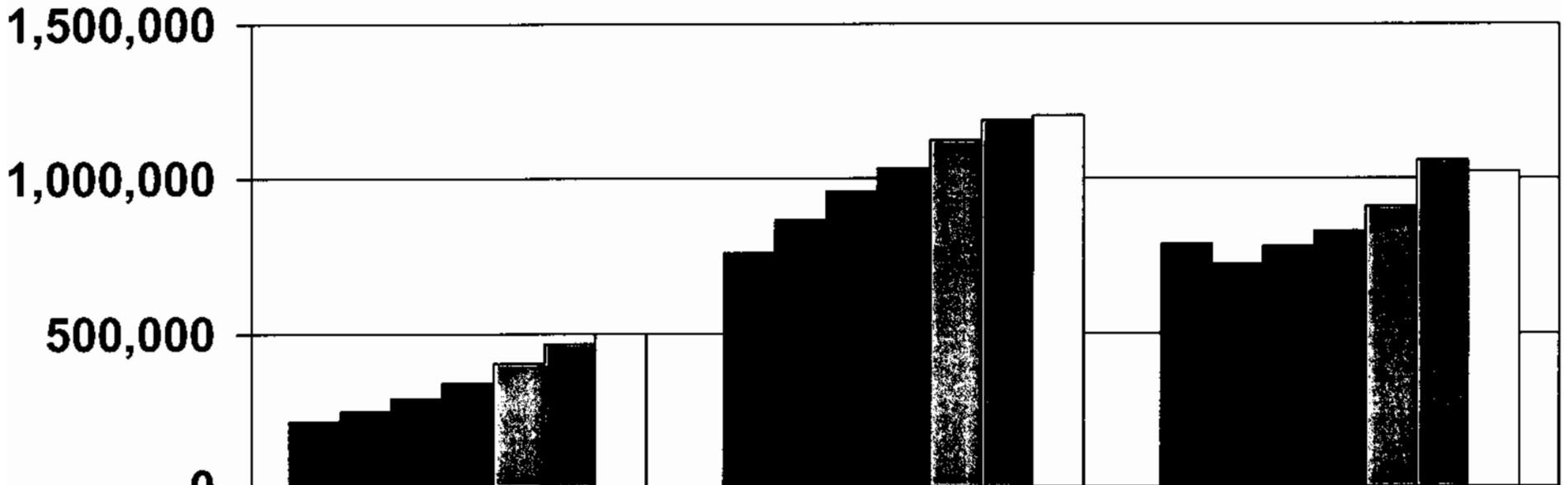
Analyze patient data and generate profiles.

Nevada Population and c/s Prescriptions



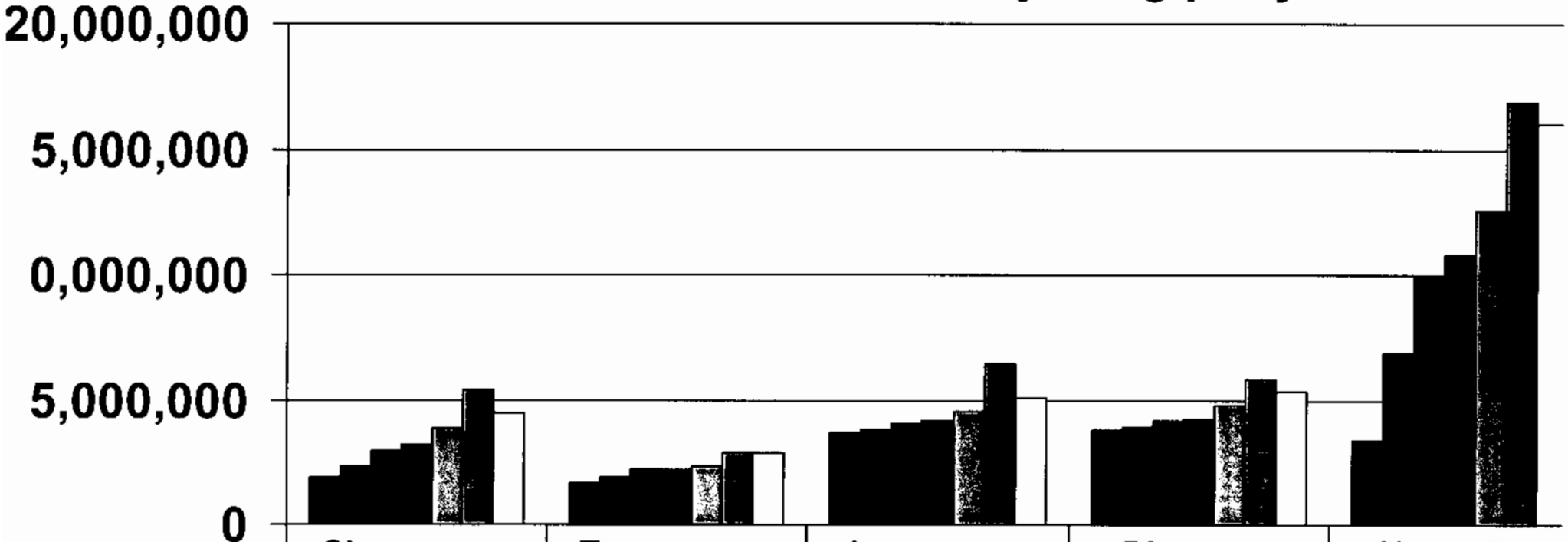
	Population	Prescriptions
1997	1,790,207	1,790,120
1998	1,870,881	1,852,164
1999	1,946,366	2,036,739
2000	2,023,378	2,215,801
2001	2,132,498	2,452,623
2002	2,206,022	2,732,939
2003	2,296,566	2,722,440

Controlled Substance Prescriptions by Schedule per year



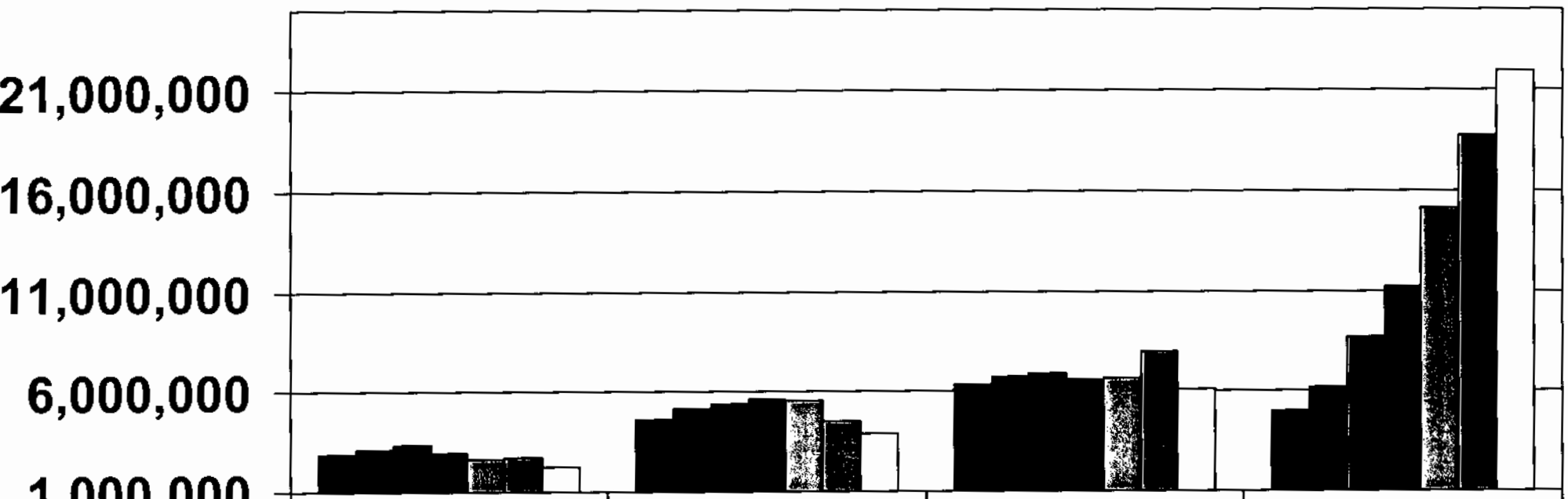
	Schedule 2	Schedule 3	Schedule 4
■ 1997	212,919	762,762	786,115
■ 1998	245,727	866,778	723,730
■ 1999	289,542	959,407	779,955
■ 2000	339,224	1,033,729	830,777
■ 2001	399,642	1,124,721	913,129
■ 2002	468,536	1,188,585	1,058,087
□ 2003	498,666	1,203,217	1,020,557

Controlled Substance Doses by Drug per year



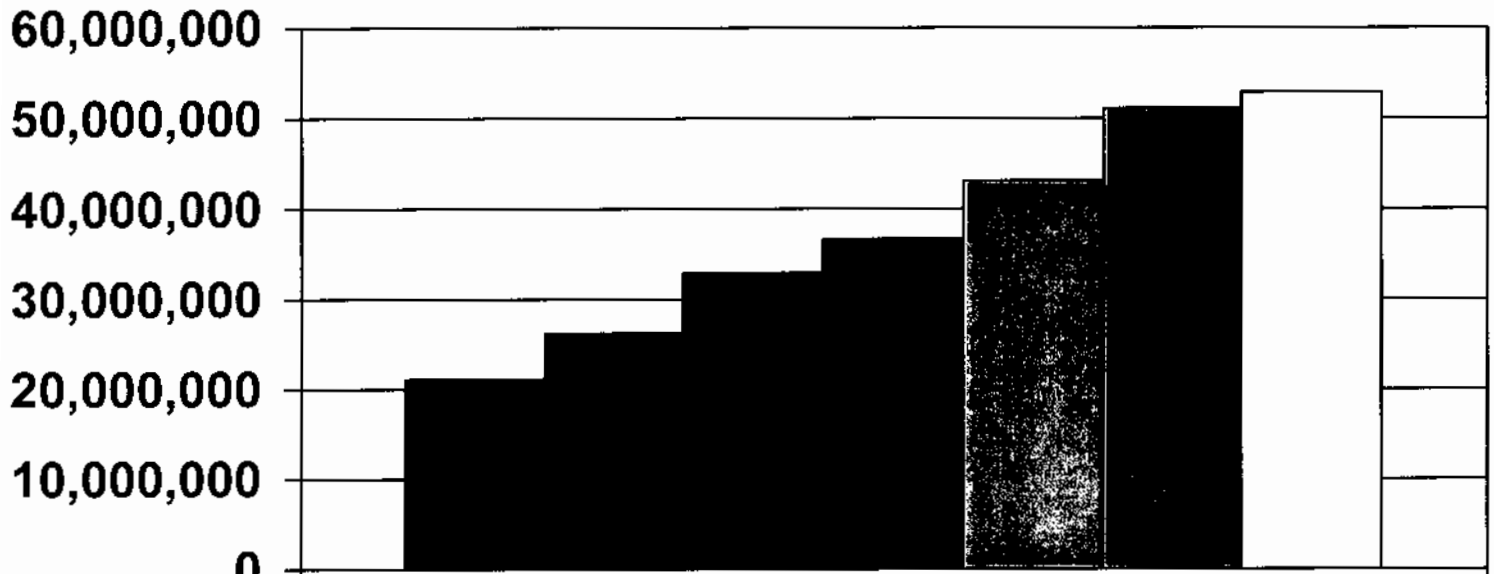
	Clonazepam	Temazepam	Lorazepam	Diazepam	Alprazolam
■ 1997	1,910,284	1,652,722	3,709,169	3,813,176	3,369,304
■ 1998	2,358,478	1,902,422	3,805,778	3,896,470	6,900,590
■ 1999	2,964,470	2,182,908	4,031,624	4,174,759	9,942,082
■ 2000	3,171,882	2,218,946	4,160,892	4,224,929	10,811,813
■ 2001	3,845,108	2,358,135	4,556,022	4,782,544	12,596,259
■ 2002	5,383,283	2,910,099	6,468,458	5,821,517	16,855,757
□ 2003	4,479,080	2,907,513	5,081,644	5,331,593	15,982,737

Controlled Substance Doses by Drug per year



	Methylphenidate	Codeine	Propoxyphene	Oxycodone
■ 1997	2,910,906	4,629,745	6,350,666	5,027,008
■ 1998	3,136,868	5,140,857	6,762,630	6,200,337
■ 1999	3,329,421	5,426,871	6,861,353	8,693,809
■ 2000	2,929,462	5,598,818	6,564,233	11,223,463
■ 2001	2,675,893	5,541,205	6,618,183	15,112,471
■ 2002	2,710,146	4,510,016	8,010,314	18,748,161
□ 2003	2,259,771	3,898,627	6,123,888	21,935,169

Controlled Substance Doses by Drug per year



	Hydrocodone
1997	21,132,185
1998	26,115,821
1999	32,854,622
2000	36,733,698
2001	43,103,353
2002	51,064,238
2003	52,915,100

Vicodin, Lortab, Norco

Program Operation

Reports

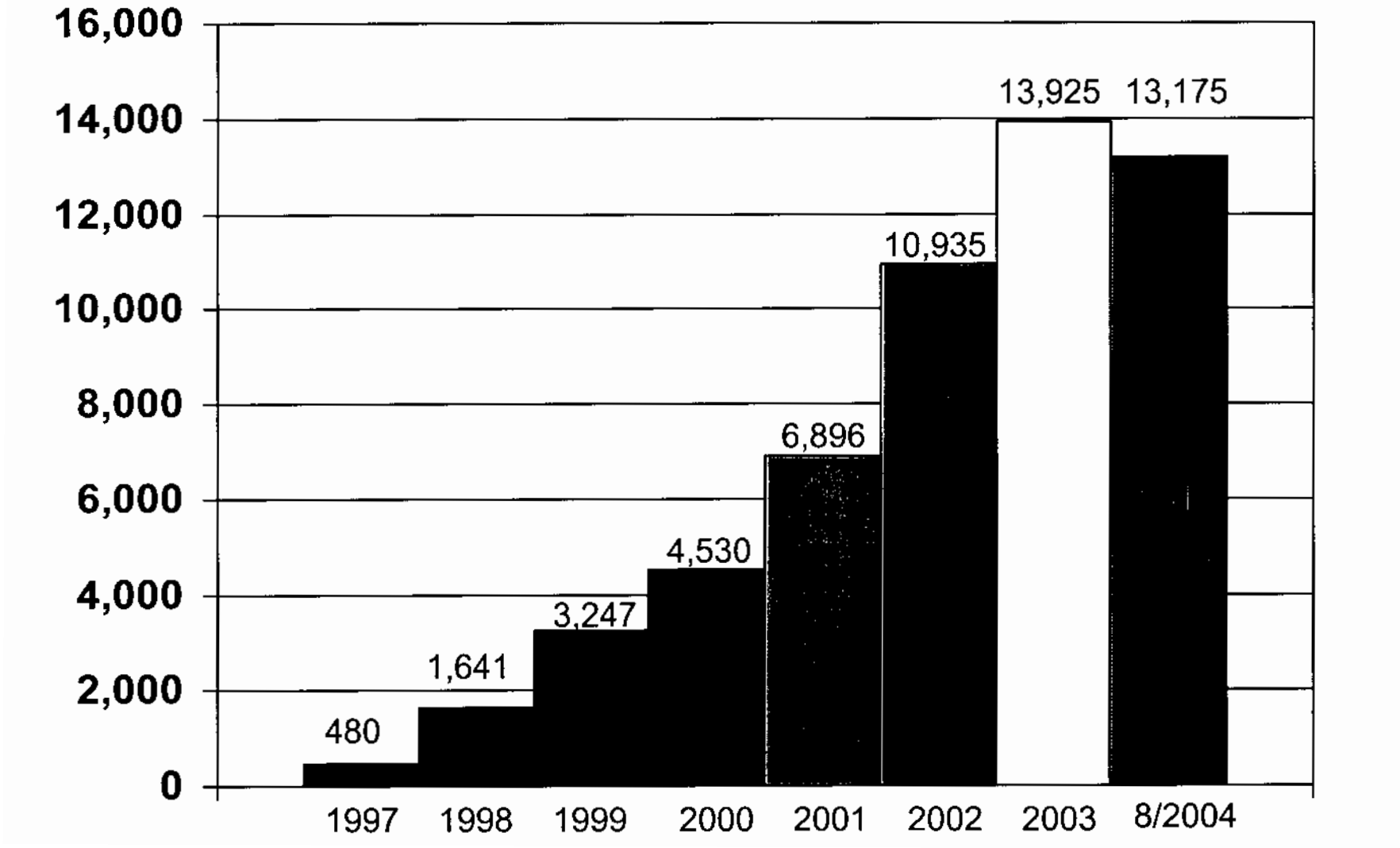
Solicited – Patient Drug Utilization Reports
- by practitioner
- by pharmacies
- by law enforcement
- by patients

Unsolicited – Patient Drug Utilization Report
Generated by Task Force office

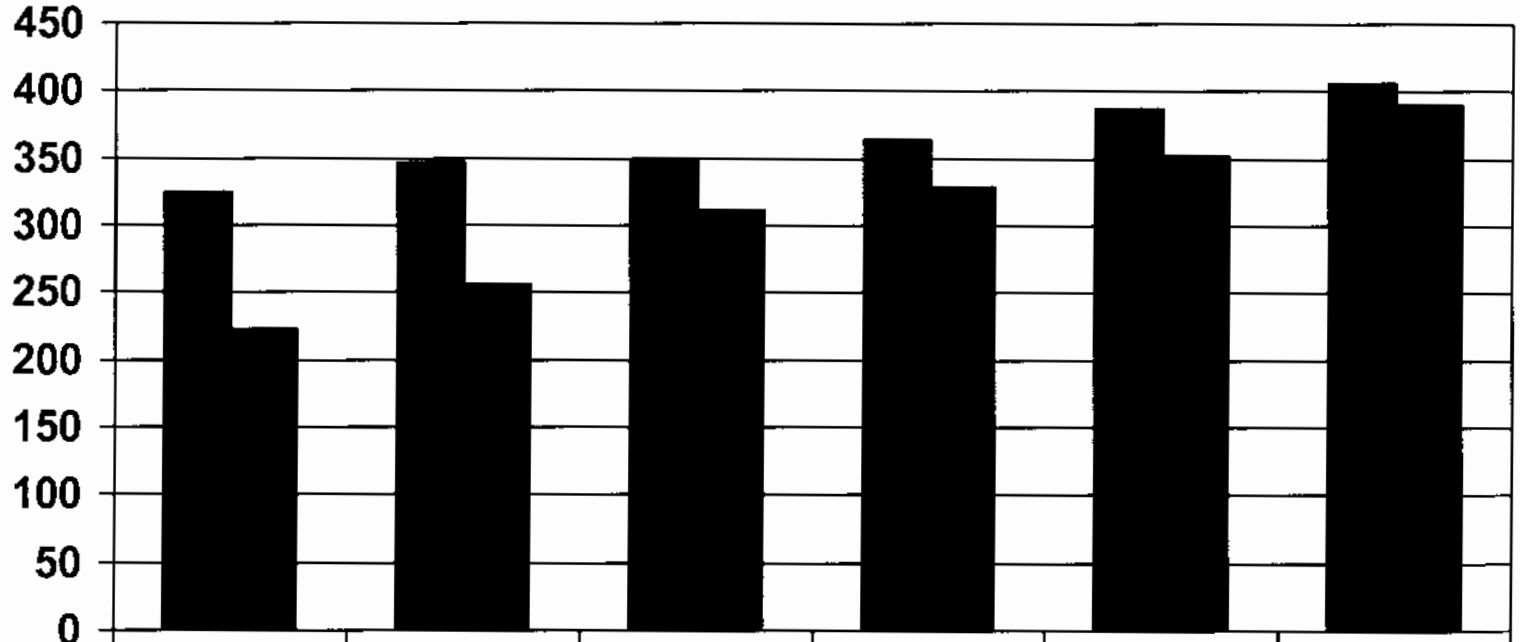
Special Reports
- Licensing boards
- Law enforcement
- By practitioners

AdHoc Reports
- By specific drugs
- Geographic distribution

Number of DUR's Requested by Practitioners/Pharmacies (solicited reports)

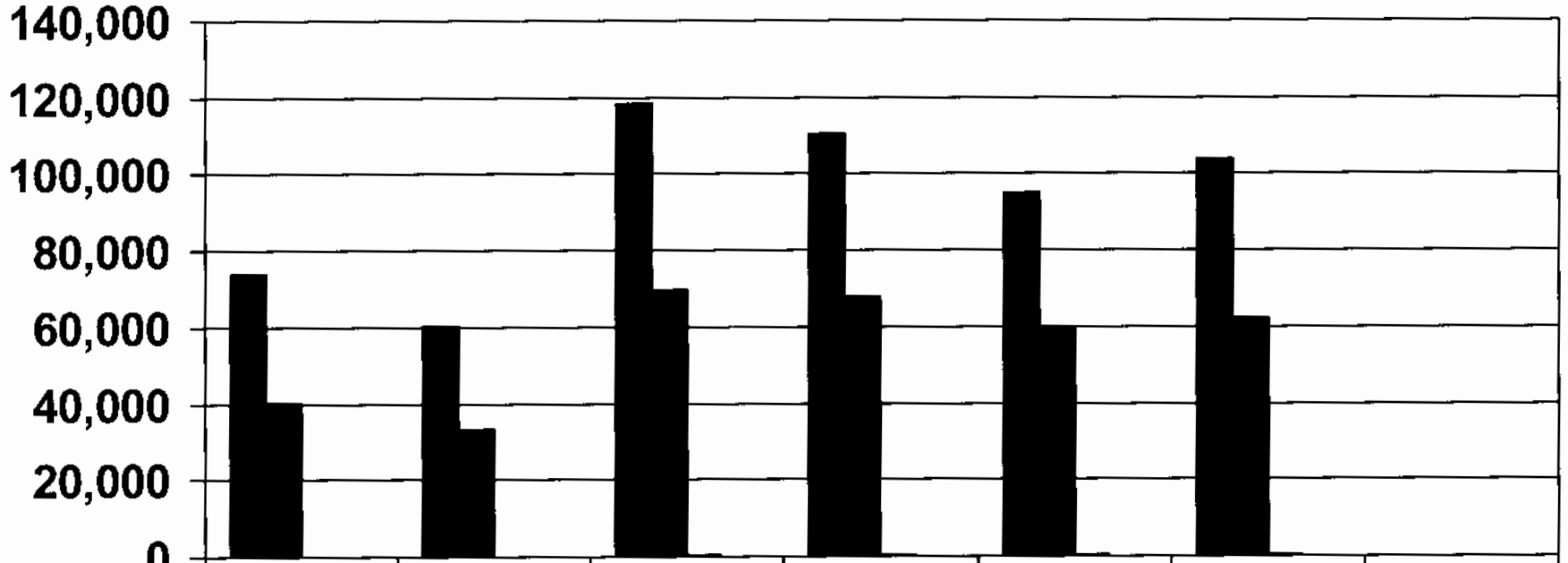


Pharmacy Reporting Data vs received unsolicited profiles



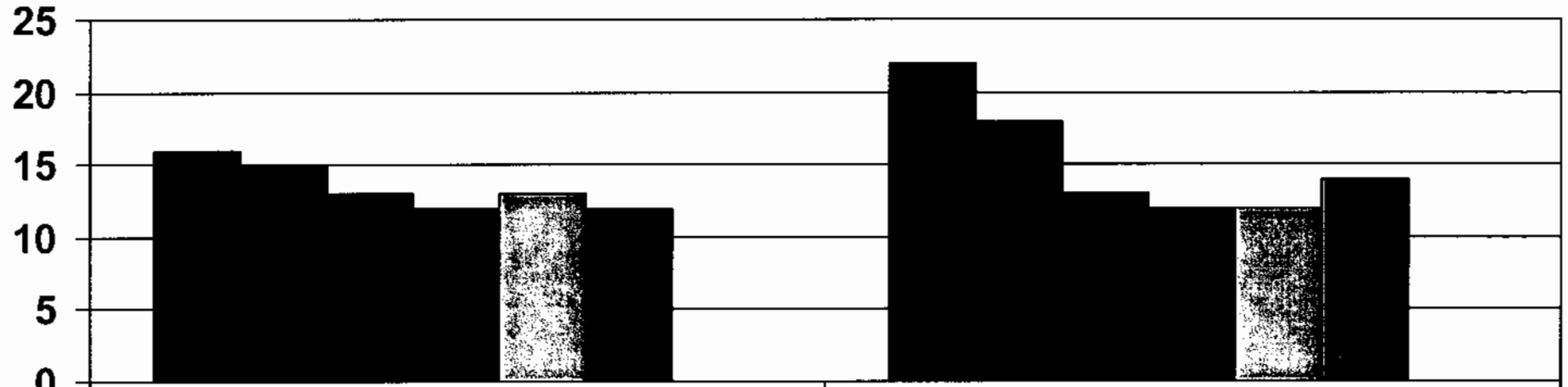
	1997	1998	1999	2000	2001	2002
■ Reporting data	325	347	350	364	387	406
■ Receiving unsolicited profiles	223	256	312	329	353	391

Unsolicited Reports
Patients, pre and post rx's



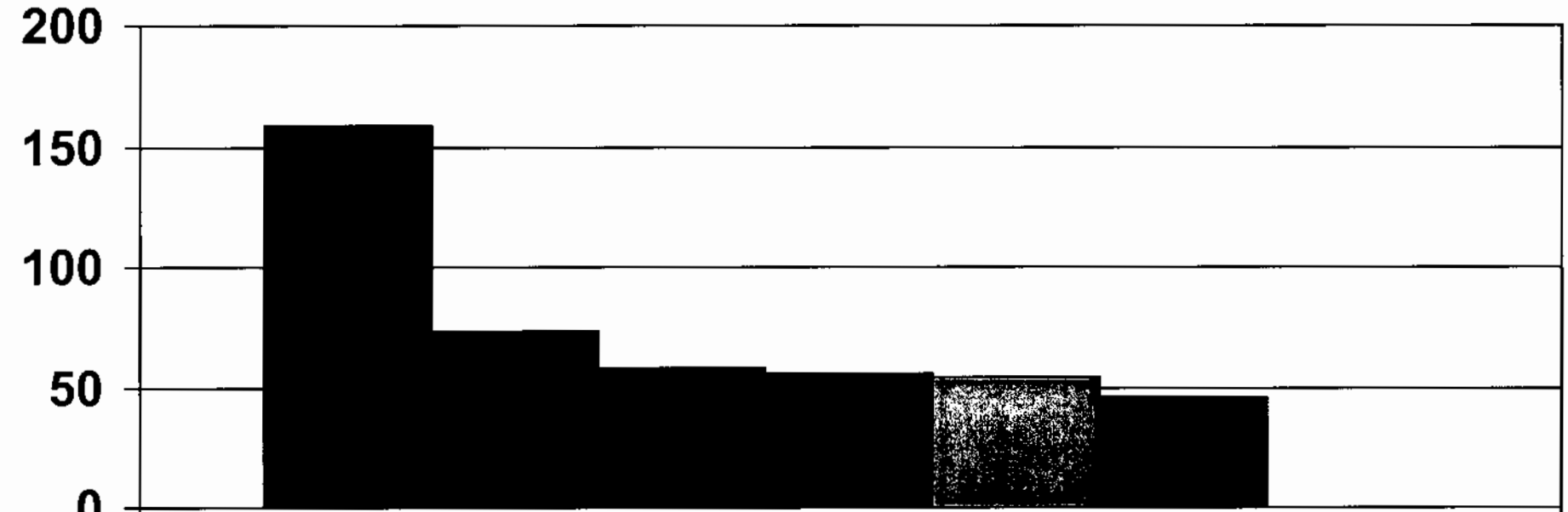
	1997	1998	1999	2000	2001	2002	2003
■ Pre-profile doses	74,000	60,348	118,554	110,598	94,952	104,137	
■ Post-profile doses	40,272	33,420	69,597	68,125	59,942	62,143	
■ # patients	182	162	475	481	559	652	
□ Avg % of decline	46%	55%	41%	38%	37%	40%	

Doctor Shoppers
Average pharmacies/practitioners



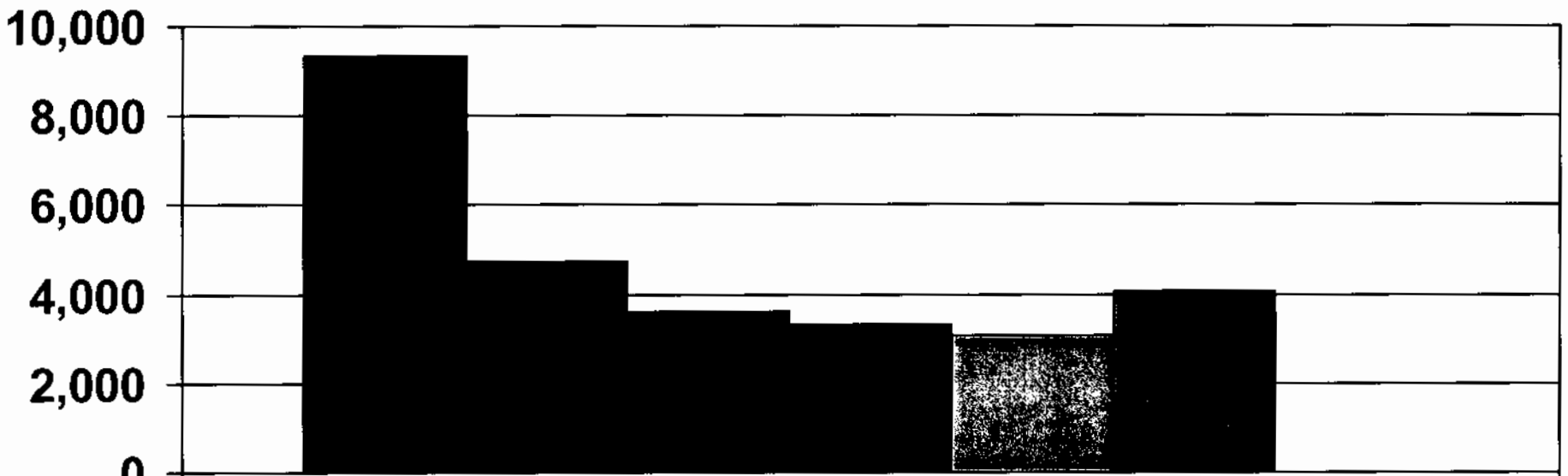
	avg # pharmacies	avg # practitioners
1997	16	22
1998	15	18
1999	13	13
2000	12	12
2001	13	12
2002	12	14

Doctor Shoppers
Average # of prescriptions received



	Avg # rx's
1997	159
1998	73
1999	58
2000	56
2001	54
2002	46
2003	

Doctor Shoppers
Average # of doses received



	Ave # doses
1997	9,351
1998	4,714
1999	3,590
2000	3,314
2001	3,081
2002	4,056
2003	

Contact Information

Keith W. Macdonald, Executive Secretary
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